

**EPA Reg. No. 2596-178**  
**Vol. 1**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Date: June 26, 2015

OPP Decision Numbers: 494679, 494678

EPA Reg. Nos.: 2596-179, 2596-178

Product Names: Hartz Reference # 144 (2596-179), Hartz Reference # 143 (2596-178)

EPA Receipt Date: August 25, 2014

EPA Company Number: 2596

Company Name: The Hartz Mountain Corporation

W. Lance H. Hemsarh  
Senior Director, R&D  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, New Jersey 07094

Subject: Confirmation of Request to Withdraw an Application

Dear Mr. Hemsarh:

This is to confirm that the Agency has received and processed your request of June 18, 2015 to withdraw the above referenced application. Since we received your request to withdraw this application more than 60 days from the beginning of the decision review period, the Agency has determined that based on the work completed at the time the application was withdrawn, 0% of the amount paid will be refunded. Any future submission related to this action must be submitted as a new application that requires the appropriate fee.

If you have questions concerning this letter, please contact the Pesticide Registration Fee Ombudsperson, Mr. Stephen Schaible at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script that reads "Susan T. Lewis".

Susan Lewis, Director  
Registration Division (7505P)  
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

6/17/2015

W. Lance H. Hemsarh  
Senior Director, R&D  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, New Jersey 07094

Subject: R340: Efficacy to add new claims  
EPA Reg. No.: 2596-178  
Product Names: Hartz Reference #143  
Application Date: 3/18/2015  
PRIA Due Date: 7/1/2015  
Decision Numbers: 494678

Dear Mr. Hemsarh;

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

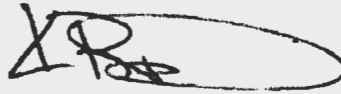
- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Autumn Metzger at 703-305-5314 or Metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3  
Invertebrate and Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs

Attachments





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

**To:** Autumn Metzger

**From:** Kevin Sweeney, Senior Entomologist

**Through:** Pesticide Evaluation Review Committee (PERC)

**Date:** June 11, 2015

**Subject:** PRODUCT PERFORMANCE DATA EVALUATION RECORD

**This is a primary review of a rebuttal containing additional efficacy data for this registration action.**

**DP barcodes:** 426808 and 426809

**Decision Nos.:** 494935 and 494679

**Submission Nos:** 965920 and 965921

**Action code:** R340

**Product Names:** Hartz Reference #143 and #144

**EPA Reg. Nos:** 2596-178 and 2596-179

**Formulation Type:** pet spot-ons

**Ingredients statement from the label with PC codes includes:**

2596-178 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

2596-179 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

**Application rate(s) of product:** linear dose increments depending upon the weight range as directed by the label.

2596-178 = product dose range from lowest weight class is 0.67 ml (0.023 fl. oz.) (5 lbs) to 4.02 ml (0.136 fl. oz.) (132 lbs.) for the highest weight class.

2596-179 = 1.5 ml (0.051 fl. oz.) applied to cats weighing 3 lbs or more.

**Use pattern:**

2596-178 is a spot-on for dogs. Apply in a continuous band along the dorsal midline from head to tail.

2596-179 is a spot-on for cats. Apply in a single spot between the shoulder blades on the back of the cat.

## **OCSPP/OPPTS Guidelines: OPPTS 810.3300.**

**I. Action Requested:** Review raw study report data associated with previously cited and reviewed public literature in support of a label amendment. Registrant has requested that the following claims be added to the labels of both products:

**“Controls flea infestations on treated cats (and kittens) (&kittens) and prevent infestations in the home.”**

**“Prevents fleas on treated cats (and kittens) (&kittens) from infesting (reinfesting) your home”**

**II. Background:** The cited literature (nine articles) presented data on a variety of insecticide combinations applied as a spot on to pets. Hartz wishes to use those data to support the above claims, which indicate that applying their product to a pet will control /prevent flea infestations in the home/indoor premises. EPA and Hartz met on October 14, 2014 to discuss these claims and the data needed to support them. Hartz presented a discussion on a new study to EPA and EPA provided input on the study design during the meeting and in a protocol review. Concurrently, Hartz advised EPA that an amendment was pending that included literature to support the above label claims. Instead of relying on the proposed study results, they requested EPA to review the cited published literature to support the claims. EPA advised Hartz that public literature does not stand-alone, but may be used as part of a weight of the evidence approach to supplement a study testing the label claims for control and prevention of fleas in the home.

Subsequently, I reviewed the cited studies on January 8, 2015. I concluded that the cited studies were not sufficient to stand-alone in support of the proposed label claims. My recommendations included “... *The last three studies by Dryden were the most relevant citations but this published literature did not provide the raw data or meet the requirements of GLP. Furthermore, the studies were not conducted with the subject product or with a product that is substantially similar to the subject product.*” In response, Hartz requested – and was granted – an extension of the PRIA date during which time they submitted the study report for literature item 8 below in the attached Appendix.

### **III. Study Report Review:**

Hartz submitted an original study report to supplement the literature cited in Item 8 (see below in Appendix) in order to provide raw data and document study findings. This study was conducted with two registered products (Frontline Plus) containing fipronil (insecticide/adulticide) and S-methoprene (IGR). The subject product contains fipronil (insecticide/adulticide), S-methoprene (IGR), and pyriproxyfen (IGR).

**Study Report: VS-USA-28730**

**MRID49593901. Dryden, M., S. J. Gross, and D. Carithers. 2010. Evaluation of the Efficacy of Frontline Plus for the Control of Flea Populations and Flea-Gender Analysis in Heavily Flea Infested Private Residences and Populations on Naturally Infested Pets in**

## **Tampa, Florida, 13 Years after Fipronil Introduction.**

**Background:** In 1997, one year following product introduction, Frontline Top Spot was assessed in households in the Tampa area. Twelve years later in 2009 this study was performed with Frontline Plus to assess the continued efficacy of fipronil-based products against fleas in the Tampa, Florida area. In the interval between the two studies, retrospective observations were made on retained flea trap samples from household studies, noting that over time, the gender ratio of the flea population tended to shift from predominantly female (or at least 50:50) to predominately male as the flea infestation was being eliminated by on-animal flea control. This study was designed to examine and document these trends on a large scale to help evaluate the success of the flea control program with Frontline. (Note: EPA did issue an EUP for Top Spot in the late 1990s. Much of that data supported current Merial product uses.)

**Purpose:** determine the impact of appropriate on-animal treatments made to all pets in the household on premise flea populations, flea gender ratio, and on-animal flea burdens.

### **Materials and Methods:**

**Location:** The study was conducted in Tampa, Florida.

**Test substance/Product:** fipronil (9.8% w/w)-(S)-methoprene (8.8% w/w) and cats were treated with fipronil (9.8% w/w)-(S)-methoprene (11.8% w/w) (Frontline®Plus for dogs and cats, EPA Reg. Nos. 65331-5 and -4, respectively.)

**Test substance/Product application:** All pets (dogs and cats) were weighed and Frontline Plus was applied to them according to label directions. Treatments were made on Day 0 and Day 28-30. No other topical or premise treatments were made during the study. More detail provided in treatments descriptions below.

**Pest species: cat flea, *Ctenocephalides felis*.**

**Study design:** This was a non-randomized, non-controlled, non-blinded, field study to evaluate the effect (impact) of Frontline Plus on flea emergence/control and flea gender ratios in heavily infested homes in the Tampa area.

**Experimental unit:** Each household was considered an experimental unit for site assessment of flea emergence and gender ratios. Each animal was considered an experimental unit for on-animal flea assessments.

**Animals:** the pets (dogs and cats only) used in this study were homeowner owned. (Note: animals had to be qualified for the study as described in the criteria below. It appears that in some cases not all animals qualified.)

**Criteria for household inclusion:** 29 homes and their respective pets were selected in the Tampa area in the summer of 2009. The inclusion criteria were:

1. Fleas present on pets (minimum of five fleas).
2. Fleas present in home (based upon on at least 5 fleas in KSU intermittent flea light traps).
3. One to four healthy dogs or cats (no more than four).
4. Owner agreed to participate for at least two months.
5. Owners willing to not use any other premise or topical flea treatment during the study.
6. Owner signed consent forms.
7. Owners understood there were no restrictions on the animals regarding exposure to rain, swimming or movement outdoors.
8. No mammalian pets other than dogs or cats in the household.

**On-Animal Product Treatments:** Dogs were treated topically according to label dosing recommendations; the entire dose was applied on one spot between the shoulder blades for dogs or on the neck for cats. Pets were weighed on Days -1 or 0 to ensure proper dosing. All pets in each enrolled household were treated on Day 0 and then once between Days 28-30. All treatments were applied by study investigators. No other topical or premise flea treatments were used during the study. There were no restrictions on the animals with regard to exposure to rain, swimming or movement outdoors. However, while pet activity was not be restricted, it was recorded. It should be noted that in some homes with multiple dogs and/or cats not all pets qualified for inclusion in the study (fewer than 5 fleas, inability to examine, etc). However, all qualifying and non-qualifying dogs and cats within each enrolled household were still administered weight/species appropriate treatment.

**Premise Flea Population Assessment:** The numbers of adult fleas emerging in the home were assessed using intermittent light traps<sup>1</sup>. Two traps were placed in two distinctly separate rooms/areas for 16 to 24-h for each household assessment period. Light trap site selection was based on where the pet(s) spend most of their time or where owners had observed fleas. Once trap locations were selected for a household, the traps were returned to those same locations for each subsequent counting period. Fleas collected on the adhesive pads of the traps were enumerated and identified as to characteristics (e.g.; fed, unfed, gravid) and as to species. In addition, the gender of fleas collected by light traps for each counting period, for each household, was determined. Environment flea counts were conducted + 1 day on Days 0, 7, 14, 21, then once between Days 28-30, 40-45, and 54-60.

**On-Animal Flea Population Assessments:** The flea population densities on each pet were estimated using a visual area count methodology (hand counts)<sup>2</sup>. Area counts were performed at five locations on each animal; dorsal midline, tail head, left lateral, right lateral and inguinal region. Area counts were limited to one minute per location and conducted by parting the hair against the lay using both hands until the selected area was covered. Animal flea count estimates were conducted + 1 day on Days 0, 7, 14, 21, then once between Days 28-30, 40-45, and 54-60.

<sup>1</sup> Dryden M, Broce A. Development of a flea trap for collecting newly emerged *Ctenocephalides felis* (Siphonaptera: Pulicidae) in homes. J. Med. Entomol. 30:901-906, 1993.

<sup>2</sup> Dryden M, Boyer J, Smith V. Techniques for estimating on-animal populations of *Ctenocephalides felis* (Siphonaptera: Pulicidae). J. Med. Entomol. 31:631-624, 1994.

**Flea in Premise) Control Assessments:** Percentage of control achieved by the flea products were calculated using Geometric Means (GM) and the following formula:

$$\frac{(\text{Day } z \text{ GM Flea trap Counts} - \text{Day } y \text{ GM Flea trap Counts})}{\text{Day } z \text{ GM Flea trap Counts}} \times 100 = \% \text{ control}$$

Where z = Day 0, or the Day with the highest number of fleas collected (red-line homes)

Where y = Day 54-60 (completion date of household)

To determine these geometric means, counts were transformed to the natural logarithm of (count + 1) for calculation.

There were also a subset of homes where an increase in trap counts of at least 125% over Day 0 counts was seen within thirty days following product application on Day 0 (identified in data tables as red-line homes). To address this issue, a second measure for control assessment was performed. In these analysis, using the formula noted, the highest trap total count seen in the first 4 weeks for each household (not necessarily Day 0) was compared to the final trap count for that household. These assessments were performed including all fleas found in the flea traps - fed or unfed. The Geometric Mean Flea Counts of unfed fleas captured in these traps were assessed in the same manner as total fleas captured in the trap. Day 0 to final count, and highest count to final count.

**Gender-Ratio Assessments:** Fleas collected in traps were assessed for gender throughout the study, noting the arithmetic ratio of female to male fleas (f:m) for each study site. Additionally, arithmetic ratios of only unfed fleas found in the traps were assessed.

**On-Animal Flea Counts:** On-animal flea count estimates of live adult fleas were transformed to the natural logarithm of (count + 1) for calculation of geometric means by assessment group at each time point. Percent reduction from the control (Day 0) mean were calculated using the formula  $[(C - T) / C] \times 100$ , where C = geometric mean for the control count (Day 0) count and T = geometric mean for the treated group for each subsequent assessment (Days 0, 7, 14, 21, then once between Days 28-30, 40-45, and 54-60).

#### Statistics:

**Data transformation:** As discussed above, this study transformed count data. Count data (e.g., number of individuals or species) are often log-transformed to satisfy parametric test assumptions. Apart from the fact that generalized linear models are better suited in dealing with count data, a log-transformation of counts has the additional quandary in how to deal with zero observations. With just one zero observation (if this observation represents a sampling unit), the whole dataset needs to be "adjusted" by adding a value (usually 1) before transformation.

**Flea control/reduction assessment:** To compare the reductions in flea counts in traps from Day 0 to Day 54-60 and from "maximum count to Day 54-60, the final count value was subtracted from the starting value, and the difference was transformed to the natural logarithm of (count+1)

*1); if the final count was higher than the initial count, causing a negative "reduction" the difference was defined as equal to zero.* A t-test was then performed on the transformed differences with a null hypothesis that the mean difference was equal to zero; 2-sided p-values were reported.

**Gender ratio:** To compare the sex ratio of all fleas or unfed fleas in traps on Day 6 to that on Day 54-60, a test of two independent proportions was used; 2-sided p-values were reported. Flea counts on the pets were summarized for each site by calculating geometric means for each site and day as described for trap counts; maximum count for each animal or each site was not determined. Geometric means overall and for each type of site were calculated as described for trap counts, with each site having equal weight in the calculation, and percent reduction from Day 0 to Day 54-60 was calculated as described above for trap counts. The p-value for the difference between Day 0 and Day 54-60 flea counts was determined the same as for trap counts.

### **Study Results:**

Data from twenty-seven households were analyzed in these assessments. Premise flea control and flea gender-ratio assessments were calculated based upon the total numbers of fleas found in the flea traps, and separately by the number of unfed fleas present in the flea traps. On animal flea counts were based on total estimates.

The authors presented data from a 60 day EUP-like field study where every animal (dog and/or cat) received two monthly treatments of FrontLine products. The report focused on the impact (measured by % reduction based on geometric mean counts from flea trap collections) of these treatments on premise flea populations in areas most commonly occupied by the pets such as a resting or sleeping site. Second, the effect of these treatments on flea gender ratios and blood feeding was examined. On-animal counts were also reported. Data were presented in table form with raw data reports located in appendices. The authors also provided special consideration to the most heavily infested households where flea counts actually increased at the beginning of the study.

Flea trap counts for the total fleas captured for each collection date were converted to the geometric mean and the percent control was calculated based on the geometric mean counts seen in the traps at Day 0. By the end of the study (Day 54-60), the percent reduction from Day 0 flea trap counts was 89.2%, with homes described as red-line homes (sites where the count increased by >25% within the first 30 days) experiencing 77.3% reduction and normal homes (sites where the count did not rise over 25% within the first 30 days) a 94.9% reduction of flea burdens was seen (Table 2). In all cases, the reductions seen were all statistically significant ( $p < 0.05$ ). When percent reduction at the end of the study was calculated based upon the geometric mean of the final count against the geometric mean of the highest flea trap burden measured within the first 30 days of the study, the efficacy for all households was 93.3%, with the red-line home reduction at 91.8% and a reduction of 95.1% was seen in the normal homes (Table 2). These reductions too, were all statistically significant ( $p < 0.05$ ). These same assessments were measured, only counting fleas that were unfed and in the traps, excluding any fleas that had taken a blood meal. When measuring reductions from Day 0 for unfed fleas the total was 85.4%, red-

line homes were 69.7% and normal homes were 93.1%. When reductions were measured against the high burden present in the first thirty days, the unfed flea total was 92.5%, red-line homes measured 90.9% and the normal homes were 94.5% (Table 3). Again, all reductions were statistically significant  $p < 0.05$ ).

<b>Table 2. Geometric mean TOTAL flea (<i>Ctenocephalides felis</i>) trap counts and reduction from control (Day 0) and reduction from maximum trap count, from infested households where all dogs and/or cats are treated with FRONTLINE Plus</b>									
	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60	% reduction from Day 0	% reduction from maximum trap count'
All Homes	13.5	6.9	9.8	6.8	4	2.8	1.5	89.20%*	93.30%*
-red line homes	11.9	10.5	17.3	10.8	5.1	5.1	2.7	77.30%*	91.80%*
-normal homes	14.9	4.8	6.1	4.6	3.2	1.6	0.8	94.90%*	95.10%*

\*Reduction observed was statistically significant ( $p < 0.05$ )

I reviewed the raw data presented in this study report and calculated the mean flea count for each day for each group of homes as presented in Table 2a below. The % reduction values for all homes is based on a weighted average because there were 12 red line homes and 15 normal homes. The arithmetic means tends to be more sensitive to outliers as evidenced by the data reported in days 40-45 where one home had 267 fleas. The geometric mean provides a measure more like a median value or one of central tendency.

Table 2 a. (Reviewer calculated from raw data). **Arithmetic mean** of TOTAL flea (*Ctenocephalides felis*) trap counts and reduction from control (Day 0) and reduction from maximum trap count, from infested households where all dogs and/or cats are treated with FRONTLINE Plus.

	Day 0	Day 7	Day 14	Day 21	Days 28-30	Days 40-45	Days 54-60	%reduction from Day 0 at days 54-60	% reduction from maximum trap count +
All Homes								83.6	85
-red line homes only (12)	13.25	17.6	29.8	20.58	7.5	26.6***	3.83	72%	70%
-normal homes only (15)	20.26	8.4	8.4	7.6	4.73	2.8	1.6	93%	97%

\*\*\* Home # 7 had 267 fleas collected. This home had one pet.

+ Mean highest infestation day through day 30 is 42.5. The highest average infestation count occurred most frequently on Day 14.

Table 3. Geometric mean <i>UNFED</i> flea ( <i>Ctenocephalides felis</i> ) trap counts and reduction from control (Day 0) and reduction from maximum trap count, from infested households where all dogs and/or cats are treated with FRONTLINE Plus									
	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60	% reduction from Day 0	% reduction from maximum trap count
All Homes (27)	6.7	3.8	6.3	4.9	2.4	2.4	1.0	85.4%*	92.5%*
-red line homes only (12)	5.8	5.6	12.0	7.9	3.0	4.3	1.7	69.7%*	90.9%*
-normal homes only (15)	7.6	2.7	3.7	3.3	2.0	1.4	0.5	93.1%*	94.5%*

\*Reduction observed was statistically significant ( $p < 0.05$ )

**Gender-Ratio Assessments:** The total number of fleas captured in the flea traps were assessed for gender and results recorded. Using these data the gender distribution for the total flea population present in the flea traps was assessed. In all homes, at and near initiation of the study, the gender most represented in the capture traps were female fleas, representing 57.9-66.5% of the captured flea population. By the end of the study, the female fleas represented only 42.3% of the captured flea population. This same trend was seen when the houses were segregated into the red-line homes (females representing 67.3%-70.8% in initial counts, falling to 37.0% by study end). These reductions for the total homes and redline homes were statistically significant ( $p < 0.05$ ). Although less apparent, a gender shift was still seen in the normal homes (53% falling to 35.7% by day 40-45, however this percentage rose by study end due in part to the low infestation levels and presence of fed female fleas) (Table 4). However, when these same assessments were measured, counting only fleas that were unfed and in the traps, excluding any fleas that had taken a blood meal, the gender-shift seen on all homes and red-line homes, when counting unfed fleas were statistically significant ( $p < 0.05$ ). In all homes, at and near initiation, the gender distribution for the unfed flea population was weighted toward the female fleas, representing 57.5% to 59.3% of the captured flea population. By the end of the study, female flea representation fell to only 25% of the total population captured. This same trend was more pronounced in the red-line homes, starting out a bit higher at 62%-65.8% and finishing the study a bit lower at 21.4% of the captured population, and slightly less pronounced in the normal homes (53% falling to 33%), and not a significant change ( $P = 0.179$ ) in these homes (Table 5).

Table 4. Percentage of TOTAL flea ( <i>Ctenocephalides felis</i> ) population comprised by female fleas, in flea traps placed in infested households where all dogs and/or cats were treated with FRONTLINE Plus							
	% female fleas of total fleas collected						
	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60
All Homes	57.9%	66.5%	50.6%	39.9%	54.1%	42.8%	42.3%*



-red line homes only	67.3%	70.8%	47.8%	36.3%	56.9%	43.8%	37.0%*
-normal homes only	53.0%	58.6%	58.7%	42.4%	47.8%	35.7%	52.0%*

\*Reduction observed from Day 0 to Day 54-60, was statistically significant ( $p < 0.05$ )

**Table 5.** Percentage of *UNFED* flea (*Ctenocephalides felis*) population comprised by female fleas, in flea traps placed in infested households where all dogs and/or cats were treated with FRONTLINE Plus

	% female fleas of total fleas collected						
	Day 0	Day 7	Day 14	Day 21	Day 28-30	Day 40-45	Day 54-60
All Homes	57.5%	59.3%	44.7%	32.2%	41.4%	40.0%	25.0%*
-red line homes only	65.8%	62.0%	42.5%	26.8%	42.0%	41.2%	21.4%*
-normal homes only	53.4%	53.8%	51.3%	39.0%	40.8%	30.8%	33.3%*

\*Reduction observed from Day 0 to Day 54-60, was statistically significant ( $p < 0.05$ )

**On-Animal Flea Counts:** Most homes had one pet but some had as many as 3-4. The number of fleas on each pet for each reporting period was reported but whether a pet was a cat or dog was not reported and cat and dog data were not reported separately or analyzed. Instead data were pooled per household for overall calculation of the geometric means for every reporting period for every household. The red-line homes had a total of 23 pets while the normal homes had a total of 27 pets. The all homes data are based on flea collected from a sample size of 50 pets across 27 households. Normal homes showed the most consistent decreases in flea counts after the second product application through 60 days. The red-line homes data were less consistent and the flea load per animal did not differ for some of the animals, which may be due to picking up more fleas outside at these households. Outdoor flea counts were not performed.

Based on the data reported in the appendix, the on-animal flea count estimates for each count date were converted to the geometric mean and the percent control was calculated based on the geometric mean counts seen on animals at Day 0. By the end of the study (Day 54-60), the percent reduction from Day 0 counts for pets from all households in the study was 87.5%. The percent reduction in counts for pets in homes described as red-line homes (sites where the household trap counts increased by 25% within the first 30 days) experiencing 69.7% reduction and normal homes (sites where the trap counts did not rise over 25% within the first 30 days) a 95.0% reduction of on animal flea burdens was seen. All geometric mean count reductions from Day 0 to Day 54-60 were statistically significant ( $p < 0.05$ ). The data show that there was an initial reduction in flea counts on the animals.

**IV. Entomologist's Conclusions:** The data provided showed that appropriate (monthly) on-animal treatments with Frontline Plus to a total of 50 dogs and cats reduced – but did not eliminate – premise flea populations by 60 days in 27 homes. The treatments results in 82% or greater control of fleas based on arithmetic means and nearly 90% if the assessment is based on the geometric means. Twelve houses reduced fleas by less than these values while 15 houses were better. These treatments also affected the gender ratio of female to male fleas, which resulted in a smaller population of females. On-animal treatments were slightly better than

expected in some homes and excellent in others. Geometric means were calculated in this study because there were no control treatments as these were EUP like trials in human occupied homes where they wanted to eliminate fleas. The products used in this study were not the same as the subject product and neither product contained pyriproxyfen. However, the products used in this test contained an equal or lesser amount of S-methoprene and the same amount of fipronil as the subject product.

#### **V. Entomologist's Recommendations:**

1. The data were submitted to amend the subject labels in order to add the following claims:

**“Controls flea infestations on treated cats/dogs (and kittens/puppies) (&kittens/puppies) and prevent infestations in the home.”**

**“Prevents fleas on treated cats/dogs (and kittens/puppies) (&kittens/puppies) from infesting (reinfesting) your home”**

The study results indicate that the on-animal product treatments of Frontline Plus:

- Reduced flea premise populations. The data had higher variability in the red-line homes compared to the normal homes.
- Controlled flea infestations on most treated pets. Dogs and cats were not identified but the claim is supported based on the wealth of data on these and related products.

2. Based on the above, the claims “Prevents infestations in the home” and “Prevents fleas from infesting (reinfesting) your home” are not supported. There was considerable variability in the results and mean fleas counts indicate that fleas were not eliminated in the treatments.

**APPENDIX - For PERC review I attached the results of the first review below.**

**Reviews and recommendations from DER dated January 8, 2015.**

**The registrant submitted nine public literature citations in one MRID that were reviewed as follows on January 8, 2015.**

**MRID49455301. Volume 1: Supplemental Information - White Paper. "Submission of Laboratory and Field Studies to Confirm Topical Parasiticide Applications Control Pre-Existing In-Home Flea Infestations and Specific Support of In-Home Infestation Control Claims for EPA Reg. Nos. 2596-178 and -179."**

The white paper included the following citations. I included the registrants' explanations from their white paper.

**"1. Jacobs, D. E., M. J. Hutchinson, D. Ewald-Hamm. 2000. Inhibition of immature *Ctenocephalides felis felis* (Siphonaptera: Pulicidae) development in the immediate environment of cats treated with imidacloprid. *Journal of Medical Entomology* 37 (2): 228-230.**

Jacobs et al. (2000) showed that treated cats had transferred sufficient imidacloprid residues to blankets after a 6 hour contact per day, for 5 days. A new blanket was used each week for 4 weeks. Pre-adult flea viability on blankets was reduced by 100%, 84%, 60% and 74% in the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> week after treatment, respectively.

**Entomologist's Conclusion: Unacceptable. The product tested was not similar to the subject product.**

**2. Jacobs, D. E., M. J. Hutchinson, D. Stanneck. 2001. Accumulation and persistence of flea larvicidal activity in the immediate environment of cats treated with imidacloprid. *Medical and Veterinary Entomology* 15: 342-345.**

In another study, Jacobs et al. (2001) used the same test design except for increasing the contact periods to 10 or 20 6-hour blanket contact periods over 2 and 4 weeks, respectively. Results showed that the degree of control was significantly higher after 26 days achieving pre-adult flea control of 100% and 97.4% after 10 or 20 days of blanket exposure, respectively.

**Entomologist's Conclusion: Unacceptable. This study was conducted with an imidacloprid based formulation that was not similar to the subject product.**

**3. Ross, D. H., R. G. Arther, C. von Simson, V. Doyle, M. W. Dryden. 2012. Evaluation of the efficacy of topically administered imidacloprid + pyriproxyfen and orally administered spinosad against cat fleas (*Ctenocephalides felis*): Impact of treated dogs on flea life stages in a simulated home environment. *Parasites & Vectors* 5:192.**

Ross et al. (2012) evaluated pre-adult flea control of an orally administered ectoparasiticide versus a topical imidacloprid/pyriproxyfen application. Dogs were housed in pens with floor mats that could be sampled for flea development. Flea infestations were established on-animal 1, 16 and 21 days prior to ectoparasiticide administration. Results showed topical application of the imidacloprid/pyriproxyfen formula resulted in transfer of active ingredients to floor matting. After only 1 week of exposure to treated dogs, floor mat samples provided better than 95% control of adult flea emergence.

While laboratory studies have shown the ability of treated pets to transfer effective amounts of active ingredient within simulated home environments, the same transfer of parasiticide active ingredients under in-home conditions has been demonstrated through field testing.

**Entomologist's Conclusion: Unacceptable.** This study was conducted with a formulation that contained spinosad.

**4. Dryden, M. W., H. Perez, and D. Ulitchny. 1999. Control of fleas on pets and in homes by use of imidacloprid or lufenuron and a pyrethrin spray. JAVMA 215 (1):39-39.**

Dryden et al. (1999) investigated existing household flea infestations. The ability for topical parasiticides and oral parasiticides to control in-home infestations was evaluated. It is critical to note that other flea treatments, either applied to the pets or their surrounds, were not used during the study. As well, no restrictions were made regarding exposure of pets to rain, swimming and outdoor activity. Results showed the incidence of fleas on pets and pre-adult flea populations living in the home were reduced by the topical parasiticide application containing imidacloprid. On-animal flea control was achieved within 1 week and in-home infestation was reduced by 86.8% after 4 weeks.

**Entomologist's Conclusion: Unacceptable.** The product tested was not similar to the subject product as it contained an IGR and adulticides not present in this formulation.

**5. Dryden, M. W., J. M. Denehberg, S. Bunch. 2000. Control of fleas on naturally infested dogs and cats and in private residences with topical spot applications of fipronil or imidacloprid. Vet Parasitol. 93: 69-75.**

In a follow up study, both fipronil and imidacloprid were evaluated for on-animal and infestation control potential. The same conditions existed for no other pesticide treatments being during the test as well as no restrictions on pets' activities or movement. Results showed on-animal control was achieved for both active ingredients after 1 week. In-home infestation control was as well achieved for both active ingredients exceeding 89.0% after 4 weeks. (Dryden et al. 2000).

Infestation control for both of these studies confirms transfer of active ingredients from treated the in-home environment to control pre-adult flea infestations.

**Entomologist's Conclusion: Supplemental.** One of the adulticides, fipronil, is present in the formulation at the same level but a complete data set was not provided. Furthermore, the author relied on visual hand counts for assessing flea infestation levels on the animal instead of comb counts.

**6. Maynard, L. P. Houffschmitt, and B. Lebreux. 2001. Field efficacy of a 10 percent pyriproxyfen spot-on for the prevention of flea infestations on cats. Journal of Small Animal Practice 42: 491-494.**

Maynard et al. (2001) evaluated an IGR only application and the effects it had on in-home flea infestations. Topical application of a 10% pyriproxyfen formula resulted in flea infestation control, measured by 'zero-flea' cats, increasing through the study from 49% control on day 30 to 88% control on day 180. In this study, no restrictions were placed on pets' activities including movement outdoors. It was concluded that appropriately timed topical applications of pyriproxyfen offer a method of flea control in the domestic environment.

**Entomologist's Conclusion: Unacceptable.** The formulation is not similar to the subject product and amount of pyriproxyfen applied to the cats is not equivalent to the dose to be delivered by the subject product.

**7. Dryden, M. W., P. Payne, v. Smith, B. Riggs, J. Davenport, and D. Kobuszewski. 2011a. Efficacy of dinotefuran-pyriproxyfen-permethrin and fipronil-(S)-methoprene topical spot-on formulations to control flea populations in naturally infested pets and private residences in Tampa, FL. Vet. Parasitol. 182:281-286.**

Dryden et al. (2011a) repeated an in-home field trial methodology to investigate a dinotefuran/pyriproxyfen/permethrin topical formula versus topically applied fipronil/(S)-methoprene. The fipronil/(S)-methoprene formula provided in-home pre-adult infestation control greater than 88% after 4 weeks. Greater than 96% was achieved after 6 and 8 weeks showing progressive in-home infestation control over time with monthly treatments.

**Entomologist's Conclusion: Supplemental.** The data from the dinotefuran-pyriproxyfen-permethrin formulation are not relevant to this amendment. The data from the fipronil-methoprene combination products provide supporting data that may be useful in a weight of the evidence approach as the concentration of fipronil and methoprene are similar to the subject product. However, these data cannot stand-alone as they are not complete data sets. The % control at 30 days is less than 90% (Study Table 1).

**8. Dryden, M.W., D. Carithers, A. McBride, B. Riggs, L Smith, J. Davenport, V. Smith, P. Payne, S. Gross. 2011b. A comparison of flea control measurement methods for tracking flea populations in highly infested private residences in Tampa FL, following topical treatment of pets with Frontline® Plus(Fipronil/(S)-Methoprene). Intern J. Appl. Res. Vet. Med. 9:356-367.**

Dryden et al. (2011b) made an assessment of extremely high in-home flea populations with reinfestation pressure from outside environments. A fipronil/(S)-methoprene formula was tested. Significant flea populations existed in the homes studied. Heavy pressure from outdoor wild animal sources existed. With this constant pressure, over the 60 day study, the percent reduction in unfed adult flea emergence from Day 0 and from maximum trap counts in all homes studied were 85.4% and 92.5%, respectively. Under these excessive test conditions, reduction in flea egg production and the transfer of ectoparasiticide active ingredients in the home by treated pets provided significant infestation control.

**Entomologist's Conclusion: Supplemental.** The product tested a Merial product containing a similar level of methoprene and fipronil. The data were not collected with the subject product and complete data sets are not available. This citation may be useful in a weight of the evidence approach to supplement a product specific study.

**9. Dryden, M. W., P. Payne, V. Smith, M. Chwala, E. Jones, J. Davenport, G. Fadl, M. F. Martinez-Perez de Zeiders, K. Heaney, P. Ford, F. Sun. 2013. Evaluation of indoxacarb and fipronil (S)-methoprene topical spot-on formulations to control flea populations in naturally infested dogs and cats in private residences in Tampa FL. USA. Parasites & Vectors 6:366.**

Dryden et al. (2013) also made comparison of formulas containing fipronil/(S)-methoprene versus indoxacarb. The study was done in naturally infested homes. Infestations were noted as the highest ever recorded in Tampa, Florida. Over 2 months, results showed the in-home pre-adult flea infestation control achieved for indoxacarb and fipronil/(S)-methoprene formulas were 97.7% and 84.6%, respectively.

**Entomologist's Conclusion: Supplemental for reasons stated for the previous study.**

#### **Hartz Conclusions:**

"All studies, both laboratory as well as field studies, document in-home pre-adult flea infestation control can be achieved by topical ectoparasiticide treatments. Specifically, laboratory testing under simulated home conditions have substantiated that effective residues of ectoparasiticide formulas do transfer from treated pets to surrounding surfaces. As seen from field trials, those residues in addition to the reduction

in viable eggs being laid on-animal are sufficient to provide pre-adult flea infestation control in the home even under severe adult flea re-infestation pressure.

As for the three field trials discussed above evaluating fipronil/(S)-methoprene topical formulas, and cats were treated with fipronil (9.8% w/w)-(S)-methoprene (8.8% w/w) and fipronil (9.8% w/w)-(S)-methoprene (11.8% w/w), respectively. Results showed flea infestations in the home environment were reduced by over 88% in 4 weeks, by over 92% from peak population counts over 2 months and by over 84% in 2 months. Even with constant heavy pressure from the outside environment, monthly re-applications of a fipronil/(S)-methoprene formula, and no secondary environmental pesticide applications, in-home flea infestations that existed prior to test product application were controlled over a 1 to 2 month period (Dryden et al. 2011a, 2011b, 2013).

These 3 field studies are submitted specifically in support of the claims,

"Controls flea infestations on treated (insert pet) and prevent infestations in the home."

"Prevents fleas on treated (insert pet) from infesting (reinfesting) your home." for EPA registration 2596-178 and 2596-179."

**Entomologist's Conclusion:** The Dryden et al. studies provide supplemental evidence that transfer of S-methoprene and fipronil may take place in the home. Light trap data were used to survey for fleas but visual hand-counts on the animal were also used. These studies do not meet GLP requirements and were not conducted under an Experimental Use Permit.

**Entomologist's Recommendations:**

**1. The cited literature provides supplemental information on the ability of pet spot-on products to control/prevent fleas in the home environment. However, these citations do not stand alone. A GLP experiment must be conducted to show that this product performs as claimed. Therefore, the proposed claims are not acceptable based on citation of literature.**

The last three studies by Dryden were the most relevant citations but this published literature did not provide the raw data or meet the requirements of GLP. Furthermore, the studies were not conducted with the subject product or with a product that is substantially similar to the subject product.



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800  
REGULATORY AFFAIRS

March 18, 2015

**49593900**

FedEx Next Day and via Electronic-mail

Document Processing Desk (Davis/ PM3)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: Hartz Reference #143, EPA Reg. No. 2596-178  
Response to Product Performance DER, Jan. 8, 2015, Decision No. 494678  
Additional data, MRID 49455301, DER item III.8

Dear Ms. Metzger,

Thank you for taking the time to discuss this submission of additional information. The review of the public literature cited above asked for the raw data. Enclosed is the full report we received from Merial supporting the journal article identified as item 8 in the DER cited above. It is the summary and raw data from the study.

In this package please find these items dated March 18, 2015:

1. Cover letter, original
2. Transmittal document
3. Application for Pesticide Registration, EPA Form 8570-1 (3 copies)
4. Certification with Respect to Citation of Data
5. Data Matrix
6. Data Matrix (confidential public copy)
7. No Claim of Confidentiality
8. Study with raw data (3 copies)

EPA Reg. No. 2596-178, additional information

March 18, 2015

Page 2

This letter confirms that the article cited in MRID 49455301, item III.8. titled "A comparison of flea control measurement methods for tracking flea populations in highly infested private residences in Tampa FL, ..." from the Inter J. Appl. Res. Vet. Med. 9:356-367 is the retitled version of the study enclosed. The full report with data enclosed "Evaluation of the Efficacy of Frontline Plus for the Control of Flea Populations and Flea-Gender Analysis in Heavily Flea Infested Private Residences and Populations on Naturally Infested Pets in Tampa FL, 13 Years After Fipronil Introduction" is the report upon which that article is based.

Thank you for your time and efforts in evaluating this additional data. If I may be of any assistance in your review, please feel free to contact me at your convenience.

Sincerely,

A handwritten signature in black ink, appearing to read "David Jones", written in a cursive style.

David Jones

Manager Regulatory Affairs

Encl.

cc: S. McNear, L. Hemsarth



# TRANSMITTAL DOCUMENT

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**Submitter:**

The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

Company Contact:



Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

**Regulatory Action in Support of Which This Package is Submitted:**

EPA Reg. No. 2596-178; HARTZ Reference #143 response to agency request for additional information regarding public literature citations

**Submission Date:**

03/18/2015

**List of Submitted Documents:**

Cover letter  
Application Form (3 copies)  
Certification with Respect to Data  
Data Matrix  
Data Matrix, confidential public copy  
No Claim of Confidentiality Statement  
Original report with raw data (3 copies)

**49593901**

Evaluation of the Efficacy of Frontline(R) Plus for the Control of Flea Populations and Flea-Gender Analysis in Heavily Flea Infested Private Residents and Populations on Naturally Infested Pets in Tampa FL, 13 Years After Fipronil Introduction: Final Report



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 2596-178	2. EPA Product Manager K. Davis	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #143	PM# 3	
5. Name and Address of Applicant (Include ZIP Code)  The Hartz Mountain Corporation, 400 Plaza Dr. Secaucus, NJ 07094  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Response to agency request to supply report including raw data for study cited from public literature.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name David Jones		Title Mgr. Regulatory Affairs	
		Telephone No. (Include Area Code) (201) 271-4800	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature 		3. Title Manager Regulatory Affairs	
4. Typed Name David Jones		5. Date March 18, 2015	

2000





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corp., 400 Plaza Dr., Secaucus, NJ 07094; (201)271-4800	EPA Registration Number/File Symbol 2596-178
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene, Pyriproxyfen	Date March 18, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential indoor	Product Name Hartz Reference #143

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*David Jones*

Date

March 18, 2015

Typed or Printed Name and Title

David Jones/Mgr. Regulatory Affairs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M. Street, S.W.  
Washington, DC. 20460

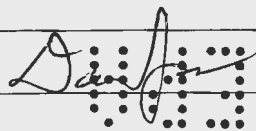
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**DATA MATRIX**

Date	November 19, 2014	EPA Reg No./File Symbol	2596-178	Page 1 of 5
Applicant's/Registrant's Name & Address	The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		Product	Hartz Reference #143
Ingredients:	Fipronil, Pyriproxyfen, S-Methoprene			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status
				Note

830.1550	Product Identity and Composition	49115702	Hartz	Own	
830.1600	Description of Materials Used to Produce the Product	49115702	Hartz	Own	
830.1620	Description of the Production Process	49115702	Hartz	Own	
830.1650	Description of the Formulation Process	49115702	Hartz	Own	
830.1670	Discussion of Formation of Impurities	49115702	Hartz	Own	
830.1750	Certified Limits	49115702	Hartz	Own	
830.1800	Enforcement Analytical Method	49115703	Hartz	Own	
830.6302	Color	49115701	Hartz	Own	Self-certification
830.6303	Physical State	49115701	Hartz	Own	Self-certification
830.6304	Odor	49115701	Hartz	Own	Self-certification
830.6314	Oxidation/Reduction Chemical Incompatibility	49223001	Hartz	Own	Waiver
830.6315	Flammability	49115701	Hartz	Own	Self-certification

Signature	Name and Title	Date
	David Jones/ Mgr. Regulatory Affairs	March 18, 2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M. Street, S.W.  
Washington, DC. 20460

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**DATA MATRIX**

Date November 19, 2014	EPA Reg No./File Symbol 2596-178	Page 2 of 5
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #143	
Ingredients: Fipronil, Pyriproxyfen, S-Methoprene		
Guideline Reference Number	Guideline Study Name	MRID Number
		Submitter
		Status
		Note

830.6316	Explosibility	49223001	Hartz	Own	Waiver
830.6317	Storage Stability	To be submitted	Hartz	Own	In progress
830.6319	Miscibility	49115702	Hartz	Own	
830.6320	Corrosion Characteristics	To be submitted	Hartz	Own	In progress
830.6321	Dielectric Breakdown Voltage	49223001	Hartz	Own	Waiver
830.7000	pH	49223001	Hartz	Own	Waiver
830.7100	Viscosity	49115701	Hartz	Own	
830.7300	Density/Relative Density/Bulk Density	49115701	Hartz	Own	
870.1100	Acute Oral Toxicity	44942004	Merial	Pay	
870.1200	Acute Dermal Toxicity	44942005	Merial	Pay	
870.1300	Acute Inhalation Toxicity	49223001	Hartz	Own	

Signature 	Name and Title David Jones/ Mgr. Regulatory Affairs	Date March 18, 2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M. Street, S.W.  
Washington, DC. 20460

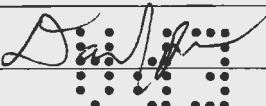
Form Approved OMB 2070-0060

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**DATA MATRIX**

Date	November 19, 2014	EPA Reg No./File Symbol	2596-178	Page 3 of 5
Applicant's/Registrant's Name & Address		Product		
The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		Hartz Reference #143		
Ingredients: Fipronil, Pyriproxyfen, S-Methoprene				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note

870.2400	Acute Eye Irritation	44942006	Merial	Pay	
870.2400	Acute Eye Irritation	48405805	Hartz	Own	
870.2500	Acute Dermal Irritation	44942007	Merial	Pay	
870.2600	Skin Sensitization	44942008	Merial	Pay	
870.4100	Acute Toxicity, Chronic toxicity	42178309	Sumitomo	FOR	
870.7200	Companion Animal Safety	44942104	Merial	Pay	
870.7200	Companion Animal Safety	45143901	Merial	Pay	
870.7200	Companion Animal Safety	45612702	Merial	Pay	
870.7200	Companion Animal Safety	45620507	Merial	Pay	
870.7200	Companion Animal Safety	49223001	Hartz	Own	Waiver
40 CFR 157. Subpart B	Child Resistant Package Testing	48684601	Hartz	Own	

Signature	Name and Title	Date
	David Jones/ Mgr. Regulatory Affairs	March 18, 2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M. Street, S.W.  
Washington, DC. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.2 hours per response for registration of activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 301 M. Street, S.W. Washington, DC 20460. Do not send the form to this address

**DATA MATRIX**

Date	November 19, 2014	EPA Reg No./File Symbol	2596-178	Page	4 of 5
Applicant's/Registrant's Name & Address		Product			
The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688		Hartz Reference #143			
Ingredients: Fipronil, Pyriproxyfen, S-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

40 CFR 157 Subpart B	Child Resistant Package Testing	48684602	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684603	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684604	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684605	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684606	Hartz	Own	
810.3300	Treatments to Control Pests of Humans and Pets	43577715	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942105	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942106	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45612701	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620501	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620504	Merial	Pay	

Signature	Name and Title	Date
	David Jones/ Mgr. Regulatory Affairs	March 18, 2015



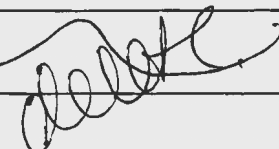
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M. Street, S.W.  
Washington, DC 20460

Form Approved OMB 2070-0060

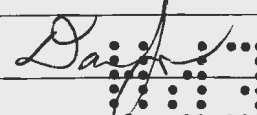
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**DATA MATRIX**

Date	November 19, 2014	EPA Reg No./File Symbol	2596-178	Page 5 of 5	
Applicant's/Registrant's Name & Address		Product			
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810.3300	Treatments to Control Pests of Humans and Pets	45620505	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620506	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866901	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866902	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	49115704	Hartz	Own	
810.3300	Treatments to Control Pests of Humans and Pets	49455301	Hartz	Public Literature	
810.3300	Treatments to Control Pests of Humans and Pets	Submitting	Hartz	PER	

910300

Signature		Name and Title	David Jones/ Mgr. Regulatory Affairs	Date	March 18, 2015
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**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision #:</b> 494678	<b>Registration #:</b> 2596-178	<b>Petition #:</b> n/a
494679	2596-179	
<input checked="" type="checkbox"/> See page 2 for additional registration entries		
<b>Chemical Name:</b> Fipronil, S-Methoprene, pyriproxyfen		
<b>Fee Category:</b> R340		<b>PRIA Decision Time Frame:</b> 4 mos
<b>Submitted by:</b> Autumn Metzger		<b>Branch:</b> OCSPP/OPP/RD <b>Date:</b> 01/20/2015
<b>Company:</b> The Hartz Mountain Corp.		
<b>Original PRIA Due Date:</b> 01/23/2015		<b>Proposed New PRIA Due Date:</b> 07/01/2015
<b>Previous Negotiated Due Dates:</b>		
<b>Is the "Fix" in-house?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		<b>If not, date "Fix" expected:</b> 03/31/2015
<b>Negotiated Due Date Reason:</b>		
<b>Additional Data Required</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input checked="" type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Other	
<b>Data Deficiencies</b>	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input checked="" type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology <input type="checkbox"/> Environmental <input type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
<b>Late Risk Assessment</b>	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	
<b>Interim Consideration</b>	<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice <input type="checkbox"/> Other – Comment Field
<b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)		
<b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input checked="" type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input type="checkbox"/>		
see below for explanation		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> 1/8/15-the product memo and 75 day deficiency letter was sent to co. 1/16/15 - co. explained they could get the raw data for one of the field studies and submit to us, co request a 60 day PRIA ext. we say no 1/20/15-co. requests PRIA extension of 90 days past guaranteed date of data giving PRIA date of 7-1-15		
<b>"75 Day" Letter sent?</b> <input checked="" type="checkbox"/> Yes, Date sent 01/08/2015 <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>		
<b>Rationale for Proposed Due Date:</b> gives RD 90 days once we receive data.		
<b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable		
<b>Approve:</b> <input checked="" type="checkbox"/>		<b>Disapprove:</b> <input type="checkbox"/>
<b>If disapproved, action to be taken:</b>		
<b>OD or DOD Signature:</b> CN=Marty Monell/OU=DC/O=USEPA/C=US		<b>Date:</b> 01/21/2015

Decision #:	Registration #:	Petition #:

**Issue(s) (describe in detail):**

- Company submitted citation of public literature to gain new efficacy claims: "kills pests in the 'home environment'"
- Efficacy review states that cited data was insufficient to support claims
- Memo and 75 day letter sent to co.
- Co. stated that they could get raw data for our efficacy team to review of "key" field study they think will be extensive and support claims and guarantees data to us by 3/31/15.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-15020151028-AM

SUBMITTED on 01/20/2015 at 03:37:34 PM by CN=Autumn Metzger/OU=DC/O=USEPA/C=US

APPROVED on 01/20/2015 at 03:54:48 PM by CN=Marietta Echeverria/OU=DC/O=USEPA/C=US

APPROVED on 01/20/2015 at 04:59:45 PM by CN=Susan Lewis/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 01/21/2015 at 07:54:11 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800  
REGULATORY AFFAIRS

January 20, 2015

FedEx and Electronic

Office of Pesticide Programs  
Registration Division (7505P)  
Attn: A. Metzger/ PM Team 3  
U.S. Environmental Protection Agency  
One Potomac Yard, 2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: Data Deficiency, EPA Reg. No. 2596-178, Decision No. 494678 and  
EPA Reg. No. 2596-179, Decision No. 494679  
Response to Letter dated January 9, 2015

Dear Ms. Metzger,

The Hartz Mountain Corporation (Hartz) is in receipt of the subject letter. After reviewing the letter and cited options we are requesting the establishment of a new PRIA due date. We are in the process of acquiring the data for one of the key field studies cited. We believe it is extensive. The tested material is essentially similar to the products at issue. With the acquisition not yet complete we propose the following timetable.

1. Additional data – By March 31, 2015 Hartz will submit the raw data and any all other relevant information obtained to the agency.
2. Extension of PRIA due date – We request the agency establish a new due date 90 days after the data is to be submitted, July 1, 2015.

We hope the agency finds this proposal acceptable. A discussion of the matter is welcomed should there be any questions or concerns.

Sincerely,

A handwritten signature in cursive script, appearing to read "David Jones".

David Jones  
Manager of Regulatory Affairs  
(201) 271-4800, ext. 7414  
Encl. – Original letter  
cc: S. McNear, L. Hemsarh



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

January 9, 2015

David Jones  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094

Subject: Data Deficiency  
EPA Reg. No. 2596-178; Decision No. 494678  
EPA Reg. No. 2596-179; Decision No. 494679  
Application Date: 8/22/2014  
EPA Receipt Date: 8/25/2014

Dear Mr. Jones:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **3/24/2015** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time.

1. The cited literature provides supplemental information on the ability of pet spot-on products to control/prevent fleas in the home environment. However, these citations do not stand alone. A GLP experiment must be conducted to show that this product performs as claimed. Therefore, the proposed claims listed below are not acceptable based on citation of literature:

- a. "Controls flea infestations on treated dogs/cats/etc. and prevent infestations in the home."
- b. "Prevents fleas on treated dogs/cats/etc. from infesting (re-infesting) your home."

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

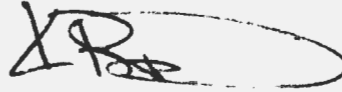
#### FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on 1/23/2015. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than 1/16/2015 to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than 1/16/2015 that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by 1/16/2015, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by 1/16/2015 by Autumn Metzger at 703-305-5314 or metzger.autumn@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, loopy oval shape.

Kable Bo Davis, Product Manager 3  
Invertebrate and Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

**From:** Kevin Sweeney, Senior Entomologist

**Date:** January 8, 2015

**Subject:** PRODUCT PERFORMANCE DATA EVALUATION RECORD

**This is a primary review.**

**DP barcodes:** 423693 and 423696

**Decision Nos.:** 494678 and 494679

**Submission Nos:** 956753 and 956754

**Action code:** R340

**Product Names:** Hartz Reference #143 and #144

**EPA Reg. Nos:** 2596-178 and 2596-179

**Formulation Type:** pet spot-ons

**Ingredients statement from the label with PC codes includes:**

2596-178 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

2596-179 = 9.8% fipronil, pc code 129121; 0.25% pyriproxyfen, pc code 129032; and 11.80% (S)-methoprene, pc code 105402.

**Application rate(s) of product:** linear dose increments depending upon the weight range as directed by the label.

2596-178 = product dose range from lowest weight class is 0.67 ml (0.023 fl. oz.) (5 lbs) to 4.02 ml (0.136 fl. oz.) (132 lbs.) for the highest weight class.

2596-179 = 1.5 ml (0.051 fl. oz.) applied to cats weighing 3 lbs or more.

**Use pattern:**

2596-178 is a spot-on for dogs. Apply in a continuous band along the dorsal midline from head to tail.

2596-179 is a spot-on for cats. Apply in a single spot between the shoulder blades on the back of the cat.

**OCSPP/OPPTS Guidelines:** OPPTS 810.3300.

**I. Action Requested:** Review cited public literature in support of a label amendment. Registrant has requested that the following claims be added to the labels of both products:

**“Controls flea infestations on treated cats (and kittens) (&kittens) and prevent infestations in the home.”**

**“Prevents fleas on treated cats (and kittens) (&kittens) from infesting (reinfesting) your home”**

**II. Background:** The cited literature presents data on a variety of insecticide combinations applied as a spot on to pets. Hartz wishes to use these data to support the above claims, which indicate that applying their product to a pet will control /prevent flea infestations in the home/indoor premises. EPA and Hartz met on October 14, 2014 to discuss these claims and the data needed to support them. Hartz presented a discussion on a new study to EPA and EPA provided input on study design. Concurrently, Hartz advised EPA that the subject amendment was pending and included claims that will be tested in the proposed study. Instead of relying on the proposed study results, they requested EPA to review and rely only on cited published literature to support the claims. EPA advised Hartz that public literature does not stand-alone, but may be used as part of a weight of the evidence approach to supplement a study testing the label claims for control and prevention of fleas in the home.

### **III. Study Review:**

**No product specific data were submitted to review. Instead, the registrant submitted a list of public literature citations.**

**MRID49455301. Volume 1: Supplemental Information - White Paper. “Submission of Laboratory and Field Studies to Confirm Topical Parasiticide Applications Control Pre-Existing In-Home Flea Infestations and Specific Support of In-Home Infestation Control Claims for EPA Reg. Nos. 2596-178 and -179.”**

The white paper included the following citations. I included the registrants’ explanations from their white paper.

**“1. Jacobs, D. E., M. J. Hutchinson, D. Ewald-Hamm. 2000. Inhibition of immature Ctenocephalides felis felis (Siphonaptera: Pulicidae) development in the immediate environment of cats treated with imidacloprid. Journal of Medical Entomology 37 (2): 228-230.**

Jacobs et al. (2000) showed that treated cats had transferred sufficient imidacloprid residues to blankets after a 6 hour contact per day, for 5 days. A new blanket was used each week for 4 weeks. Pre-adult flea viability on blankets was reduced by 100%, 84%, 60% and 74% in the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> week after treatment, respectively.

**Entomologist’s Conclusion: Unacceptable. The product tested was not similar to the subject product.**

**2. Jacobs, D. E., M. J. Hutchinson, D. Stanneck. 2001. Accumulation and persistence of flea larvicidal activity in the immediate environment of cats treated with imidacloprid. Medical and Veterinary Entomology 15: 342-345.**

In another study, Jacobs et al. (2001) used the same test design except for increasing the contact periods to 10 or 20 6-hour blanket contact periods over 2 and 4 weeks, respectively. Results showed that the degree of control was significantly higher after 26 days achieving pre-adult flea control of 100% and 97.4% after 10 or 20 days of blanket exposure, respectively.

**Entomologist's Conclusion: Unacceptable. This study was conducted with an imidacloprid based formulation that was not similar to the subject product.**

**3. Ross, D. H., R. G. Arther, C. von Simson, V. Doyle, M. W. Dryden. 2012. Evaluation of the efficacy of topically administered imidacloprid + pyriproxyfen and orally administered spinosad against cat fleas (*Ctenocephalides felis*): Impact of treated dogs on flea life stages in a simulated home environment. *Parasites & Vectors* 5:192.**

Ross et al. (2012) evaluated pre-adult flea control of an orally administered ectoparasiticide versus a topical imidacloprid/pyriproxyfen application. Dogs were housed in pens with floor mats that could be sampled for flea development. Flea infestations were established on-animal 1, 16 and 21 days prior to ectoparasiticide administration. Results showed topical application of the imidacloprid/pyriproxyfen formula resulted in transfer of active ingredients to floor matting. After only 1 week of exposure to treated dogs, floor mat samples provided better than 95% control of adult flea emergence.

While laboratory studies have shown the ability of treated pets to transfer effective amounts of active ingredient within simulated home environments, the same transfer of parasiticide active ingredients under in-home conditions has been demonstrated through field testing.

**Entomologist's Conclusion: Unacceptable. This study was conducted with a formulation that contained spinosad.**

**4. Dryden, M. W., H. Perez, and D. Ulitchny. 1999. Control of fleas on pets and in homes by use of imidacloprid or lufenuron and a pyrethrin spray. *JAVMA* 215 (I):39-39.**

Dryden et al. (1999) investigated existing household flea infestations. The ability for topical parasiticides and oral parasiticides to control in-home infestations was evaluated. It is critical to note that other flea treatments, either applied to the pets or their surrounds, were not used during the study. As well, no restrictions were made regarding exposure of pets to rain, swimming and outdoor activity. Results showed the incidence of fleas on pets and pre-adult flea populations living in the home were reduced by the topical parasiticide application containing imidacloprid. On-animal flea control was achieved within 1 week and in-home infestation was reduced by 86.8% after 4 weeks.

**Entomologist's Conclusion: Unacceptable. The product tested was not similar to the subject product as it contained an IGR and adulticides not present in this formulation.**

**5. Dryden, M. W., J. M. Denehberg, S. Bunch. 2000. Control of fleas on naturally infested dogs and cats and in private residences with topical spot applications of fipronil or imidacloprid. *Vet Parasitol.* 93: 69-75.**

In a follow up study, both fipronil and imidacloprid were evaluated for on-animal and infestation control potential. The same conditions existed for no other pesticide treatments being during the test as well as no restrictions on pets' activities or movement. Results showed on-animal control was achieved for both active ingredients after 1 week. In-home infestation control was as well achieved for both active ingredients exceeding 89.0% after 4 weeks. (Dryden et al. 2000).

Infestation control for both of these studies confirms transfer of active ingredients from treated the in-home environment to control pre-adult flea infestations.

**Entomologist's Conclusion: Supplemental.** One of the adulticides, fipronil, is present in the formulation at the same level but a complete data set was not provided. Furthermore, the author relied on visual hand counts for assessing flea infestation levels on the animal instead of comb counts.

**6. Maynard, L. P. Houffschmitt, and B. Lebreux. 2001. Field efficacy of a 10 percent pyriproxyfen spot-on for the prevention of flea infestations on cats. Journal of Small Animal Practice 42: 491-494.**

Maynard et al. (2001) evaluated an IGR only application and the effects it had on in-home flea infestations. Topical application of a 10% pyriproxyfen formula resulted in flea infestation control, measured by 'zero-flea' cats, increasing through the study from 49% control on day 30 to 88% control on day 180. In this study, no restrictions were placed on pets' activities including movement outdoors. It was concluded that appropriately timed topical applications of pyriproxyfen offer a method of flea control in the domestic environment.

**Entomologist's Conclusion: Unacceptable.** The formulation is not similar to the subject product and amount of pyriproxyfen applied to the cats is not equivalent to the dose to be delivered by the subject product.

**7. Dryden, M. W., P. Payne, v. Smith, B. Riggs, J. Davenport, and D. Kobuszewski. 2011a. Efficacy of dinotefuran-pyriproxyfen-permethrin and fipronil-(S)-methoprene topical spot-on formulations to control flea populations in naturally infested pets and private residences in Tampa, FL. Vet. Parasitol. 182:281-286.**

Dryden et al. (2011a) repeated an in-home field trial methodology to investigate a dinotefuran/pyriproxyfen/permethrin topical formula versus topically applied fipronil/(S)-methoprene. The fipronil/(S)-methoprene formula provided in-home pre-adult infestation control greater than 88% after 4 weeks. Greater than 96% was achieved after 6 and 8 weeks showing progressive in-home infestation control over time with monthly treatments.

**Entomologist's Conclusion: Supplemental.** The data from the dinotefuran-pyriproxyfen-permethrin formulation are not relevant to this amendment. The data from the fipronil-methoprene combination products provide supporting data that may be useful in a weight of the evidence approach as the concentration of fipronil and methoprene are similar to the subject product. However, these data cannot stand-alone as they are not complete data sets. The % control at 30 days is less than 90% (Study Table 1).

**8. Dryden, M.W., D. Carithers, A. McBride, B. Riggs, L Smith, J. Davenport, V. Smith, P. Payne, S. Gross. 2011b. A comparison of flea control measurement methods for tracking flea populations in highly infested private residences in Tampa FL, following topical treatment of pets with Frontline® Plus(Fipronil/(S)-Methoprene). Intern J. Appl. Res. Vet. Med. 9:356-367.**

Dryden et al. (2011b) made an assessment of extremely high in-home flea populations with reinfestation pressure from outside environments. A fipronil/(S)-methoprene formula was tested. Significant flea populations existed in the homes studied. Heavy pressure from outdoor wild animal sources existed. With this constant pressure, over the 60 day study, the percent reduction in unfed adult flea emergence from Day 0 and from maximum trap counts in all homes studied were 85.4% and 92.5%, respectively. Under these excessive test conditions, reduction in flea egg production and the transfer of ectoparasiticide active ingredients in the home by treated pets provided significant infestation control.

**Entomologist's Conclusion: Supplemental.** The product tested a Merial product containing a similar level of methoprene and fipronil. The data were not collected with the subject product and

complete data sets are not available. This citation may be useful in a weight of the evidence approach to supplement a product specific study.

**9. Dryden, M. W., P. Payne, V. Smith, M. Chwala, E. Jones, J. Davenport, G. Fadi, M. F. Martinez-Perez de Zeiders, K. Heaney, P. Ford, F. Sun. 2013. Evaluation of indoxacarb and fipronil (S)-methoprene topical spot-on formulations to control flea populations in naturally infested dogs and cats in private residences in Tampa FL. USA. Parasites & Vectors 6:366.**

Dryden et al. (2013) also made comparison of formulas containing fipronil/(S)-methoprene versus indoxacarb. The study was done in naturally infested homes. Infestations were noted as the highest ever recorded in Tampa, Florida. Over 2 months, results showed the in-home pre-adult flea infestation control achieved for indoxacarb and fipronil/(S)-methoprene formulas were 97.7% and 84.6%, respectively.

**Entomologist's Conclusion: Supplemental for reasons stated for the previous study.**

#### **Hartz Conclusions:**

"All studies, both laboratory as well as field studies, document in-home pre-adult flea infestation control can be achieved by topical ectoparasiticide treatments. Specifically, laboratory testing under simulated home conditions have substantiated that effective residues of ectoparasiticide formulas do transfer from treated pets to surrounding surfaces. As seen from field trials, those residues in addition to the reduction in viable eggs being laid on-animal are sufficient to provide pre-adult flea infestation control in the home even under severe adult flea re-infestation pressure.

As for the three field trials discussed above evaluating fipronil/(S)-methoprene topical formulas, and cats were treated with fipronil (9.8% w/w)-(S)-methoprene (8.8% w/w) and fipronil (9.8% w/w) -(S)-methoprene (11.8% w/w), respectively. Results showed flea infestations in the home environment were reduced by over 88% in 4 weeks, by over 92% from peak population counts over 2 months and by over 84% in 2 months. Even with constant heavy pressure from the outside environment, monthly re-applications of a fipronil/(S)-methoprene formula, and no secondary environmental pesticide applications, in-home flea infestations that existed prior to test product application were controlled over a 1 to 2 month period (Dryden et al. 2011a, 2011b, 2013).

These 3 field studies are submitted specifically in support of the claims,

"Controls flea infestations on treated (insert pet) and prevent infestations in the home."

"Prevents fleas on treated (insert pet) from infesting (reinfesting) your home." for EPA registration 2596-178 and 2596-179."

**Entomologist's Conclusion: The Dryden et al. studies provide supplemental evidence that transfer of S-methoprene and fipronil may take place in the home. Light trap data were used to survey for fleas but visual hand-counts on the animal were also used. These studies do not meet GLP requirements and were not conducted under an Experimental Use Permit.**

#### **IV. Entomologist's Recommendations:**

**1. The cited literature provides supplemental information on the ability of pet spot-on products to control/prevent fleas in the home environment. However, these citations do not stand alone. A GLP experiment must be conducted to show that this product performs as claimed. Therefore, the proposed claims are not acceptable based on citation of literature.**

**The last three studies by Dryden were the most relevant citations but this published literature did not provide the raw data or meet the requirements of GLP. Furthermore, the studies were not**

conducted with the subject product or with a product that is substantially similar to the subject product.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

September 05, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

THE HARTZ MOUNTAIN CORPORATION  
400 PLAZA DRIVE  
SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 25-AUG-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 8-25-14

Experts In-Processing Signature: B.B.

Date 8-27-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>2596-178</u>		EPA Receipt Date: <u>8-25-14</u>					
Items for Review					Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type				X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)						X
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)		yes	no			
	<u>*no inerts to review</u>						
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X		
	Certificate and data matrix consistent						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.						
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)						X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X		
5	a) Selective Method (Fee category experts use)		yes	no			
	b) Cite-All (Fee category experts use)						
	c) Applicant owns all data (Fee category experts use)						
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)				X		
7	Is the data package consistent with PR Notice 86-5					X	
8	Notice of Filing included with petitions						X



9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

- submitted studies FAILED PRN 11-3 Review
- no merits to review, no CSE submitted
- contacted the submitter via email on 9/2/14
- corrections were received 9/5/14 via email
- Jacket : PASSED

GAE

MRID: 494552

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

## Cipicchio, Carleigh

---

**From:** Cipicchio, Carleigh  
**Sent:** Friday, September 05, 2014 4:07 PM  
**To:** 'DJones@hartz.com'  
**Cc:** Ashe, Anthony; Correa, Leah  
**Subject:** RE: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Dave,

Thank you for sending the corrections. I will send both applications up to the appropriate product manager for further review.

Have a great weekend,

Carleigh

Carleigh Cipicchio  
EPA Contractor  
2777 S. Crystal Dr, S-4813  
Arlington, VA 22202  
ph: (703)347-0240  
[cipicchio.carleigh@epa.gov](mailto:cipicchio.carleigh@epa.gov)

**From:** DJones@hartz.com [mailto:DJones@hartz.com]  
**Sent:** Friday, September 05, 2014 11:52 AM  
**To:** Cipicchio, Carleigh  
**Cc:** Ashe, Anthony; Correa, Leah  
**Subject:** RE: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Hi Carleigh,  
I have attached the three documents requested below. Please let me know if I can provide any further support to the submissions.  
Enjoy your weekend!  
Thank you,  
Dave

David Jones  
Manager Regulatory Affairs  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094  
TEL: 201-271-4800 x 7414  
FAX: 201-271-0357

From: "Cipicchio, Carleigh" <[Cipicchio.Carleigh@epa.gov](mailto:Cipicchio.Carleigh@epa.gov)>  
To: "[DJones@hartz.com](mailto:DJones@hartz.com)" <[DJones@hartz.com](mailto:DJones@hartz.com)>,  
Cc: "Ashe, Anthony" <[Ashe.Anthony@epa.gov](mailto:Ashe.Anthony@epa.gov)>, "Correa, Leah" <[Correa.Leah@epa.gov](mailto:Correa.Leah@epa.gov)>  
Date: 09/04/2014 10:56 AM  
Subject: RE: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

---

Dave,

A Certification with Respect to Data is still required because you submitted supporting material. Since these are new submissions, a new certification will need to be generated for each product (EPA Reg #'s 2596-178 and 2596-179).

Again, please do not hesitate to contact me if you have any more questions.

Best Regards,

Carleigh

Carleigh Cipicchio  
EPA Contractor  
2777 S. Crystal Dr, S-4813  
Arlington, VA 22202  
ph: (703)347-0240  
[cipicchio.carleigh@epa.gov](mailto:cipicchio.carleigh@epa.gov)

**From:** [DJones@hartz.com](mailto:DJones@hartz.com) [<mailto:DJones@hartz.com>]  
**Sent:** Thursday, September 04, 2014 9:38 AM  
**To:** Cipicchio, Carleigh  
**Cc:** Ashe, Anthony; Correa, Leah  
**Subject:** Re: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

Good morning Carleigh,  
Thank you for the e-mail. I had not submitted a "Certification with Respect to Data" as we only summarized a set of public literature articles. Will the certification be required? If so, will a copy of the original certification filed with the initial application meet the requirement or should I generate another?  
I will sign and resend the data confidentiality page.  
Again thank you for the guidance.  
Dave

David Jones  
Manager Regulatory Affairs  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094  
TEL: 201-271-4800 x 7414  
FAX: 201-271-0357

From: "Cipicchio, Carleigh" <[Cipicchio.Carleigh@epa.gov](mailto:Cipicchio.Carleigh@epa.gov)>  
To: "[djones@hartz.com](mailto:djones@hartz.com)" <[djones@hartz.com](mailto:djones@hartz.com)>,  
Cc: "Ashe, Anthony" <[Ashe.Anthony@epa.gov](mailto:Ashe.Anthony@epa.gov)>, "Correa, Leah" <[Correa.Leah@epa.gov](mailto:Correa.Leah@epa.gov)>  
Date: 09/02/2014 04:02 PM  
Subject: Submission to EPA: Products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179)

---

Mr. Jones,

This email is to address an issue that was found regarding your applications for submission of the products Hartz Reference #143 (EPA Reg #2596-178) and Hartz Reference #144 (EPA Reg #2596-179).

In regards to product Hartz Reference #143 (EPA Reg #2596-178):

- A Certification with Respect to Citation of Data is required because you submitted studies with the application.

In regards to product Hartz Reference #144 (EPA Reg #2596-179):

- A Certification with Respect to Citation of Data is required because you submitted studies with the application.
- There was a deficiency with Volume 1 of the studies submitted:
  - MRID 49455301: You failed to sign the statement of data confidentiality claims included in the study (page 2). Please sign and resend.

Please email these corrections to me by Friday September 6. If you have any questions or concerns, please do not hesitate to contact me.

Best Regards,

Carleigh

Carleigh Cipicchio  
EPA Contractor  
2777 S. Crystal Dr, S-4813  
Arlington, VA 22202  
ph: (703)347-0240  
[cipicchio.carleigh@epa.gov](mailto:cipicchio.carleigh@epa.gov)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

DAVID JONES  
THE HARTZ MOUNTAIN CORPORATION  
400 PLAZAS DRIVE  
SECAUCUS, NJ 07094

RE: Application for Registration dated: 26-AUG-14  
Date Fee Payment: 25-AUG-14  
Product Name: HARTZ REFERENCE #143  
EPA Registration Number: 2596-178  
Decision Number: D-494678

Dear Registrant:

The Agency has completed its initial contents screen of your application pursuant to Section 33(f)(4)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended the Pesticide Registration Improvement Renewal Act. The Agency has determined that your application did not pass the initial contents screen and therefore must be rejected.

Specifically, the following items were missing or improperly formatted:  
Study volume 1 has a deficiency. You failed to sign the statement of data confidentiality claims included in the study. In addition, a statement of compliance or non-compliance with the Good Laboratory Practices Statement must address compliance or non-compliance with 40 CFR 160.

Furthermore, pursuant to FIFRA Section 33(b)(2)(G) the Agency must retain 25% of the registration service fee. Any future submissions to the Agency will be considered a new application and subject to the full registration service fee and another initial contents screen of all necessary fees, forms, data, and draft labeling.

Sincerely,

XXXXXXXXX, Director  
Office of Pesticide Programs





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 26, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-494678  
EPA File Symbol or Registration Number: 2596-178  
Product Name: HARTZ REFERENCE # 143  
EPA Receipt Date: 25-Aug-2014  
EPA Company Number: 2596  
Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES  
THE HARTZ MOUNTAIN CORPORATION  
400 PLAZA DRIVE  
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "J. Jones", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

*M*  
{956753@~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☒ Studies?      ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S-

956753

EPA File Symbol/Reg. No.

2596-178

Pin-Punch Date:

8/25/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R340

Granted:

R340

Amount Due: \$ 3,798

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

*Jennifer Gaines*

Date: 8/26/14

Remarks:

S: 956753

**Milestone Email:**

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

**Company:** 2596 THE HARTZ MOUNTAIN CORPORATION

**Risk Manager:** Registration Division, Risk Management Team 10

Product #: 2596-178

Product Name: HARTZ REFERENCE # 143

### Me Too Section 3:

**Me Too Product**  
Name:

Application Date: 22-Aug-2014

OPP Rec'd Date: 25-Aug-2014

Front End Date: 25-Aug-2014

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

**OPP Target Date:****Receipt Description:**

## AMENDMENT/STUDIES

No. 333357

**VENDOR NO:** 1992

THIS CHECK IS PROTECTED BY A VOID PANTOGRAPH, MICROPRINT, SIGNATURE LINE AND A HEAT SENSITIVE PADLOCK ICON. ADDITIONAL SECURITY FEATURES ARE LISTED ON BACK.

# Hartz:

**No. 333357**

BY



United States  
Environmental Protection Agency  
Washington, DC 20460



Registration  
Amendment  
Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 2596-178	2. EPA Product Manager R. Gebken	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #143	PM# 10	
5. Name and Address of Applicant (Include ZIP Code)  The Hartz Mountain Corporation, 400 Plaza Dr. Secaucus, NJ 07094  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. ....  Product Name .....	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated .....
<input type="checkbox"/> Resubmission in response to Agency letter dated .....	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment adding efficacy claims (2) based on a white paper supported by several public literature articles.  
Updating data matrix to incorporate MRIDs assigned for granted data waiver requests and reference white paper submission.  
Deleting claim "Made in USA". Add EPA Reg. Number  
Expanding ABNs to eliminate use of parentheses options in names

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) .....	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other .....	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Jones	Title Mgr. Regulatory Affairs	Telephone No. (Include Area Code) (201) 271-4800
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature 	3. Title Manager Regulatory Affairs	
4. Typed Name David Jones	5. Date August 22, 2014	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800  
REGULATORY AFFAIRS

August 22, 2014

FedEx Delivery

Document Processing Desk (Distribution Code-REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: Label amendment application, Hartz Reference #143, EPA Reg. No. 2596-178  
Note: Identical data (white paper) submitted concurrently for EPA Reg. No. 2596-179

Dear Sir/Madam,

Enclosed please find a pesticide registration amendment package for Hartz Reference #143. This package supports these actions:

1. Label changes
  - a. Add 2 lines claiming for home environment control of fleas (on next to last page)
  - b. Expanded the list of additional brand names (ABNs) to remove parentheses
  - c. Removed the claim "Made in USA"
  - d. Inserted the EPA Registration number assigned.
2. Additional efficacy claim - A white paper summarizing various public literature articles (public literature, copies enclosed) is tendered in support of two additional home environment efficacy claims. These statements are similar to language existing on similar products on the market today.
3. Data matrix update
  - a. Includes new MRIDs assigned since the last matrix filing
  - b. Inserted a new line at the bottom of the first page for the white paper enclosed

Enclosed is check no. 33357 payable to the US Environmental Protection Agency in the amount of \$3798 for our PRIA Code R340 submission. The same white paper is being submitted concurrently for EPA Reg. No.s 2596-178 and 2596-179.

Please call if I can answer any questions or address any concerns.

Sincerely,

David Jones  
Manager Regulatory Affairs  
(201) 271-4800, ext. 7414

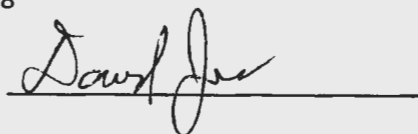
# TRANSMITTAL DOCUMENT

---

**Submitter:**

The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

Company Contact:



Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

**Regulatory Action in Support of Which This Package is Submitted:**

EPA Reg. No. 2596-179; HARTZ Reference #144; PRIA Code R340

**Amendment actions:**

- Add efficacy claims (2) based on a white paper supported by several public literature articles (copies included).
- Updating data matrix to incorporate MRIDs assigned for granted data waiver requests and reference white paper submission.
- Deleting claim "Made in USA"
- Expanding ABNs to eliminate parenthetical options in alternate product names

**Submission Date:**

08/22/2014

**List of Submitted Documents:**

Cover letter

Amendment Form

Data Matrix

Data Matrix, confidential public copy

# TRANSMITTAL DOCUMENT (cont.)

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Proposed Label Text (Five copies)

Proposed Label Text (One highlight version of prior stamped label)

PRIA Fee, Check No. 33358 for \$3798.00

**MRID #**

Volume 1 **49455301**

Transmittal document

Cover letter (copy)

Title Page

No Data Confidentiality Statement

White Paper

Referenced articles for white paper





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corp., 400 Plaza Dr., Secaucus, NJ 07094; (201)271-4800	EPA Registration Number/File Symbol 2596-178
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene, Pyriproxyfen	Date Sept. 5, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential indoor	Product Name Hartz Reference #143

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date Sept. 5, 2014	Typed or Printed Name and Title David Jones/Mgr. Regulatory Affairs
--	-----------------------	--



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date August 22, 2014		EPA Reg. No./File Symbol 2596-178		Page 1 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #143			
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	43577715	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942105	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942106	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45612701	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620501	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620504	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620505	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620506	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866901	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866902	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	Submitting	Hartz	Own	
Signature <i>David Jones</i>			Name and Title David Jones, Manager, Regulatory Affairs		Date Aug. 22, 2014

*never got revised copy by not needed it not needed*



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**DATA MATRIX**

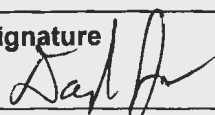

Date August 22, 2014

EPA Reg. No./File Symbol 2596-178

Page 2 of 5

Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr.,  
Secaucus, NJ 07094Product  
Hartz Reference #143

Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	49115704	Hartz	Own	
830.1550	Product Identity and Composition	49115700	Hartz	Own	
830.1600	Description of Materials Used to Produce the Product	49115702	Hartz	Own	
830.1620	Description of the Production Process	49115702	Hartz	Own	
830.1650	Description of the Formulation Process	49115702	Hartz	Own	
830.1670	Discussion of Formation of Impurities	49115702	Hartz	Own	
830.1700	Viscosity	49115701	Hartz	Own	
830.1750	Certified Limits	49115702	Hartz	Own	
830.1800	Enforcement Analytical Method	49115703	Hartz	Own	
830.6302	Color	49115701	Hartz	Own	Self-certification
Signature 			Name and Title:  David Jones, Manager, Regulatory Affairs	Date Aug. 22, 2014	


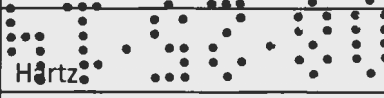


# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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## DATA MATRIX

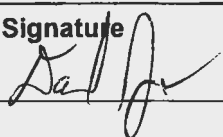
Date August 22, 2014			EPA Reg. No./File Symbol 2596-178		Page 3 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #143		
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical State	49115701	Hartz	Own	Self-certification
830.6304	Odor	49115701	Hartz	Own	Self-certification
830.6314	Oxidation/Reduction Chemical Incompatibility	49223001	Hartz	Own	
830.6315	Flammability	49115701	Hartz	Own	Self-certification
830.6316	Explosibility	49223001	Hartz	Own	
830.6317	Storage Stability	To be submitted	Hartz		In progress
830.6319	Miscibility	49115702	Hartz	Own	
830.6320	Corrosion Characteristics	To be submitted	Hartz		In progress
830.6321	Dielectric Breakdown Voltage	49223001	Hartz	Own	
830.7000	pH	49223001	Hartz	Own	
Signature 			Name and Title:  David Jones, Manager, Regulatory Affairs		Date Aug. 22, 2014



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**DATA MATRIX**

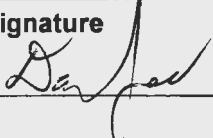
Date August 22, 2014		EPA Reg. No./File Symbol 2596-178		Page 4 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #143			
Ingredient Fipronil(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	49115701	Hartz	Own	
870.1100	Acute Oral Toxicity	44942004	Merial	Pay	
870.1200	Acute Dermal Toxicity	44942005	Merial	Pay	
870.1300	Acute Inhalation Toxicity	49223001	Hartz	Own	
870.2400	Acute Eye Irritation	44942006	Merial	Pay	
870.2400	Acute Eye Irritation	48405805	Hartz	Own	
870.2500	Acute Dermal Irritation	44942007	Merial	Pay	
870.2600	Skin Sensitization	44942008	Merial	Pay	
870.7200	Companion Animal Safety	45143901	Merial	Pay	
870.7200	Companion Animal Safety	44942104	Merial	Pay	
Signature 		Name and Title David Jones, Manager, Regulatory Affairs		Date Aug. 22, 2014	



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**DATA MATRIX**

Date August 22, 2014		EPA Reg. No./File Symbol 2596-178		Page 5 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #143			
Ingredient Fipronil(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety	45612702	Merial	Pay	
870.7200	Companion Animal Safety	45620507	Merial	Pay	
870.7200	Companion Animal Safety	49223001	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684601	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684602	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684603	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684604	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684605	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684606	Hartz	Own	
870.4100	Acute Toxicity, Chronic toxicity	42178309	Sumitomo	FOR	
Signature 			Name and Title David Jones, Manager, Regulatory Affairs	Date Aug. 22, 2014	

# DATA EXTRACTION REQUEST

Reg # 2596-178

Decision # 492405

Description: \_\_\_\_\_

## Material Sent:

☐ Electronic Label/Letter Dated \_\_\_\_\_

(See the N-drive for electronic file)

☐ Stamped Label Dated \_\_\_\_\_ (See jacket)

☐ Notification Dated \_\_\_\_\_ (See jacket)

☒ New CSF(s) Dated April 29, 2014 (See jacket)

☐ Other: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Belwanda Alexander

Division: RD

Phone: 703-305-7460

Date: \_\_\_\_\_

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 20, 2014

Mr. David Jones  
Manager Regulatory Affairs  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094

Subject: CSF Notification per PRN 98-10 –Revised Basic CSF and Alternate CSFs 1 and 2  
Product Name: Hartz Reference #143  
EPA Registration Number: 2596-178  
Application Date: April 29, 2014  
Decision Number: 492405

Dear Mr. Jones:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated April 29, 2014
- Alternate CSF 1 dated April 29, 2014
- Alternate CSF 2 dated April 29, 2014

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact BeWanda Alexander at (703)305-7460 or by email at [alexander.bewanda@epa.gov](mailto:alexander.bewanda@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez", written over a horizontal line.

Mark Suarez, Product Manager 13  
Insecticide Branch  
Registration Division (7505P)  
Office of Pesticide Programs




Decision Seq: 483630    Action Code: **R315, NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUB**

FFS Start Date: 22-Oct-2013    Tentative Ind: No    **Start/Stop Clock**    FQPA Clock:

Due Date: 22-Jul-2014    75-Day Due Date:    Days Elapsed:

OPP Target Due Date:    21-Day Due Date: 22-Oct-2013    FFS Original Decision:














Negotiated Due Date:    90-Day Due Date: 21-Jan-2014





Registrant:     Predecisional Due Date: 08-Jul-2014    Add to Bundle? ☐

Response Due Date:

Current Status: PENDING (24-Mar-2014)    Bundle ID:

- Decision Status
- Tracking
- Create Resubmission
- FFS Letters
- Waiver Documentation
- Action Code History
- Secondary Decision
- Decision Bundle

-  75 Day Letters
-  45/90 Day Screen
- Primary Decisions
- Decision Milestone
-  FFS Negotiated Due Dates
-  OPP Target Due Date
-  Decision Comments
-  Payment
-  Unmatched Payments
-  Decision Ownership
-  Receipts
-  Data Package
-  Reduced Risk
-  Meetings & Milestones
-  FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due By	Response
 949402	Petrella, Carlyn	 2596-RTI	22-Jul-2014	PENDING
Submission of updated master label.				
S: 946769	Petrella, Carlyn	 2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of additional information per 75 day deficiency letter.				
S: 941688	Petrella, Carlyn	 2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
NA				



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800  
REGULATORY AFFAIRS

May 2, 2014

Document Processing Desk (NOTIF )  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: Hartz Reference #143, EPA Reg. No. 2596-178  
Confidential Statement of Formula, addition of  
registered alternate active ingredient sources

Dear Sir/Madam,

The Hartz Mountain Corporation is submitting this application adding alternate active ingredient sources for the subject registration. This filing is consistent with conditions set forth in the Pesticide Registration Manual; Chapter 7. All active ingredients are EPA registered. The certified limits of all ingredients in the proposed alternate formulations are identical to or within the limits of the basic formulation.

Documents enclosed include:

1. Application for Pesticide, EPA Form 8570-1, dated April 29, 2014 (2 copies)
2. Confidential Statement of Formula, EPA Form 8570-4, dated April 29, 2014; Basic, Alternate #1 and Alternate #2 (1 copy each)
3. Formulator's Exemption Statement, EPA Form 8570-27, dated April 29, 2014 (1 copy)
4. Confidential Statement of Formula, EPA Form 8570-4, dated March 11, 2014; currently accepted formula (1 copy)

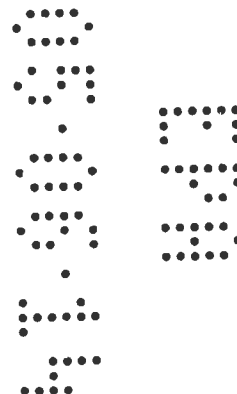
Please feel free to contact me should any questions or concerns arise. Thank you in advance for your time and consideration of this action.

Sincerely,

David Jones  
Manager Regulatory Affairs

Encl.

cc: S. McNear, E. McGarvey, H. Masch





United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 2596-178	2. EPA Product Manager R. Gebken	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #143	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Registered Sources of Active Ingredients per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand it is a violation of 18 USC Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Jones	Title Mgr. Regulatory Affairs	Telephone No. (include Area Code) (201) 271-4800
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Mgr. Regulatory Affairs	
4. Typed Name David Jones	5. Date April 29, 2014	



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
 (40 CFR 152.85)

Applicant's Name and Address  <b>The Hartz Mountain Corporation</b> <b>400 Plaza Drive</b> <b>Secaucus, NJ 07094</b>	EPA File Symbol/Registration Number <b>2596-178</b>
	Product Name <b>Hartz Reference #143</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>04/29/2014</b>

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

**Fipronil**  
**S-Methoprene**  
**Pyriproxyfen**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil		
Fipronil		
S-Methoprene		
S-Methoprene		
Pyriproxyfen		
Signature 	Name and Title <b>David Jones/ Mgr. Reg. Affairs</b>	Date <b>04/29/2014</b>

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
 Copy 2 - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*

# Material Sent for Data Extraction

Reg. # 2596-178

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 4-4-14

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 3-11-14

☐ Other: \_\_\_\_\_

☒ Decision #: 483630


☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Carmen Rodia

Phone: (703) 306-0327 Division: RD/IB

Date: 4-4-14

	<b>ENVIRONMENTAL PROTECTION AGENCY</b>  Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001	EPA Registration No.  <b>2596-178</b>	Date of Issuance:  <b>APR 14 2014</b>
<b>NOTICE OF PESTICIDE:</b> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)		Term of Issuance: <b>Conditional</b>  Name of Pesticide Product: <b>Hartz® Reference #143</b>	
<b>Name and Address of Registrant (include ZIP Code):</b> <b>The Hartz Mountain Corporation</b> <b>400 Plaza Drive</b> <b>Secaucus, NJ 07094-368</b>			
<b>Note:</b> Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p style="text-align: center;"><b>Terms of Registration</b></p> <ol style="list-style-type: none"> <li>EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment:             <ol style="list-style-type: none"> <li>Revise the EPA Registration Number to read: "EPA Registration No 2596-178"</li> </ol> </li> <li>This registration is <b>time-limited and expires two years (2) from the date this product is first released for shipment (April 4, 2016)</b>. You must provide the Agency with a projected "release for shipment date," in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.</li> <li>Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).</li> <li>Within twelve (12) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).</li> </ol>			
Signature of Approving Official:  Refer to Page #3  Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch		Date:  <b>APR 4 2014</b>	

5. You must submit the following data within the timeframe described below:  
Within twelve (12) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
6. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2014. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (attn: Kaitlin Keller).  
The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot#
  - Where purchased: internet, store, Veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred, (mm/dd/yyyy)
  - State in which the incident occurred, (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)
  - Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
7. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
  - a. All minor dermal and ocular irritation reports.
  - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
  - c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
  - d. Summary table for dogs and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
  - e. A summary table for s showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
  - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
  - g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
  - h. Table showing number of incidents for each dog breed.
  - i. Table showing number of incidents in dog for each clinical sign.
  - j. Table showing number of incidents in dog for each organ system.
  - k. Report aggregate incidents, but do not combine moderate and minor incidents.

8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
9. The Hartz Mountain Company must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site:  
<http://www.epa.gov/pesticides/health/spot-on-meetings.html>.
10. Enclosed is a copy of the data call-in (DCI) for fipronil.

You must submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records along with hard copies of the similarity clinic memo as well as the child-resistant packaging, companion animal safety data, efficacy, product chemistry reviews completed in support of the registration of this new product. If you have any questions concerning this letter, please contact Ms. Carlyn Petrella at (703) 347-0439 or via e-mail at [Petrella.Carlyn@epa.gov](mailto:Petrella.Carlyn@epa.gov).

Sincerely,



Richard Gebken  
Product Manager 10  
Insecticide Branch  
Registration Division (7504P)

Enclosures:      *Label Stamped "Accepted with Comments," dated April 4, 2014*  
                      *Child-Resistant Packaging Review, dated March 10, 2014*  
                      *Efficacy Review, dated March 18, 2014*  
                      *Product Chemistry Review, dated March 7, 2014*  
                      *Similarity Clinic Memo, dated December 11, 2013*  
                      *Copy of DCI for Fipronil*

002596-00178 D483630



April 3, 2014

## Hartz® Reference # 143

### Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)  
First Defense Pro™ for Dogs (&) (and Puppies)  
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

### FRONT PANEL

#### ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
<b>OTHER INGREDIENTS .....</b>	<b>81.15%</b>
<b>TOTAL .....</b>	<b>100.00%</b>

#### KEEP OUT OF REACH OF CHILDREN

**CAUTION:** See back panel for additional precautionary statements.

#### NET CONTENTS:

ACCEPTED  
With COMMENTS  
In EPA Letter Dated:  
April 4, 2014  
Under the Federal Insecticide, Fungicide  
and Rodenticide Act, As amended, for the  
pesticide Registered under EPA Reg. No.:  
2596-178

April 3, 2014

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



(1.5 x 1.5 cm icon)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]

DO NOT USE ON CATS

## **BACK PANEL**

### **PRECAUTIONARY STATEMENTS**

#### **HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

#### **HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

### **PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

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### FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

### READ ENTIRE LABEL BEFORE EACH USE

**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**  
**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**  
**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**  
**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**  
**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



(Place in a 1.5 x 1.5 cm yellow box with black images only.)

**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

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**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.

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#### **SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

#### **INDIVIDUAL TUBE TEXT**

*[Product name]*

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

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**OPTIONAL/ALTERNATE LABEL TEXT**

[Adult Fleas]

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Starts killing fleas within 30 minutes\* (mins)

\*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (dog or puppy or dog and puppy) that live in your home

Kills flea eggs on your (dog or puppy or dog and puppy) to prevent the eggs from hatching in your home.

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

**April 3, 2014**

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

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Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)  
Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills flea eggs and flea larvae to help prevent future re-infestations  
Kills all stages of the flea life cycle  
Breaks the flea life cycle  
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.  
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)  
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations  
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)  
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)  
Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)  
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)  
Stays on and doesn't rub off  
Kills fleas for 30 days (1 month) (4 weeks)  
Stops and prevents infestations  
Prevents re-infestation  
Prevents and controls re-infestation(s)  
Dual insect growth regulator (IGR) prevents re-infestation  
Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas  
Fast acting  
Long lasting  
Effective and convenient topical treatment  
Kills fleas (and ticks) through (after) contact  
(With) patented applicator  
Waterproof  
Effective after bathing  
Effective after exposure to water  
Easy spot on topical applicator  
Patents Pending



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Do not reapply product for 30 days  
Remains effective even after bathing, water immersion, or exposure to sunlight  
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.  
Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Fast Acting**
- **Long Lasting**
- **Waterproof**

Only for dogs and puppies 8 weeks of age or older

Specially formulated for dogs and puppies 8 weeks of age or older

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

**April 3, 2014**

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To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_

Second Dose \_\_\_\_\_

Third Dose \_\_\_\_\_

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

Decision Seq: 483630 Action Code: **R315, NEW END-USE NON-FOOD ANIMAL PRODUCT WITH 30%** ...

FFS Start Date: 22-Oct-2013 Tentative Ind: No  FQPA Clock:

Due Date: 22-Jul-2014 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 22-Oct-2013 FFS Original Decision: ...

Negotiated Due Date: 90-Day Due Date: 21-Jan-2014

Registrant:   Predecisional Due Date: 08-Jul-2014 Add to Bundle? ☐

Current Status: PENDING (04-Apr-2014) Bundle ID:

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Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Receipt
<input type="button" value="ID"/> 2596-RTI	Petrella, Carlyn	2596-RTI	22-Jul-2014	PENDING
Submission of FINAL updated master label.				
S:949987	Petrella, Carlyn	2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of further updated master label.				
S:949402	Petrella, Carlyn	2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of updated master label.				
<input type="button" value="ID"/> 2596-RTI	Petrella, Carlyn	2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT

## Rodia, Carmen

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**From:** DJones@hartz.com  
**Sent:** Thursday, April 03, 2014 4:35 PM  
**To:** Rodia, Carmen  
**Cc:** SMcNear@hartz.com; Petrella, Carolyn  
**Subject:** EPA File Symbol 2596-RTI, Hartz Ref. #143  
**Attachments:** tick Larvae Clemson.pdf; Tick Larvae Cornell.pdf; 065331-00005-20130828 p4 of 22 tick stages.pdf; L Rossi pet spot on mitigation ltr 2011 Sep 30.pdf; 2014 Apr 3 Hartz Ref 143 Master lbl.pdf

Carmen,

I appreciate your taking the time to discuss this label and comments. As mentioned, all comments are adopted except for these two we had agreed could be kept with supporting documentation:

1. Tick Larvae claim (p. 7 of 10) - As indicated, our entomologist had asserted that the tick life cycle does include a larval stage. In support he sent these two items, one tied to a link from the agency's website.

The Clemson article begins to talk about the tick larvae in the second paragraph. The Cornell article begins on page 2 under Biology and Behavior. We offer this to document the tick has a larval stage in its life cycle. The label attached for EPA Reg. No. 65331-5 upon which our data is cited shows tick larvae efficacy accepted by the agency on page 4 of 22.

2. "Immediately" (p. 3 of 10) - The partial scan of the letter from Ms. Rossi to Hartz dated Sep 30 2011 provides direction for the cat icon warning language. For the back panel the language for pet spot on products not containing permethrin, cyphenothrin nor phenothrin is given. A scan of the first and third pages of that letter is attached below.

On page 3 item 2. Back Panel a.ii. the phrase is specified. The ending of the section is matched on the attached product label "..., contact your veterinarian." This correspondence is offered to document why we used that phrase. This phrase is also consistent with the "Generic Pet Spot-On Mitigation Table", "Cat Warning language", "Other products" section on the link below.

<http://www2.epa.gov/pets/meetings-registrants-pet-spot-products>

This is the label for the subject product containing all the edits in your e-mail dated 4/2/2014 except for the two above we discussed this afternoon.

Thank you,  
Dave

April 3, 2014

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## Hartz® Reference # 143

### Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)  
First Defense Pro™ for Dogs (&) (and Puppies)  
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

### **FRONT PANEL**

#### **ACTIVE INGREDIENTS:**

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
<b>OTHER INGREDIENTS .....</b>	<b>81.15%</b>
<b>TOTAL .....</b>	<b>100.00%</b>

#### **KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See back panel for additional precautionary statements.

#### **NET CONTENTS:**

April 3, 2014

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



(1.5 x 1.5 cm icon)

*[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]*

**DO NOT USE ON CATS**

## **BACK PANEL**

### **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

### **HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

### **PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

**April 3, 2014**

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**FIRST AID**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

**READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**  
**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**  
**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**  
**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**  
**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



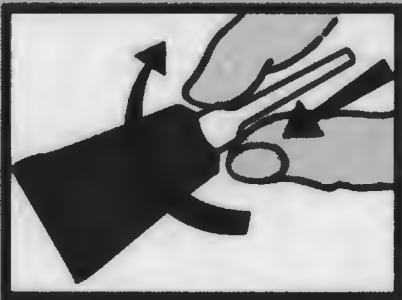
(Place in a 1.5 x 1.5 cm yellow box with black images only.)

**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

April 3, 2014



**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.



April 3, 2014

#### **SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

#### **INDIVIDUAL TUBE TEXT**

*[Product name]*

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

April 3, 2014

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**OPTIONAL/ALTERNATE LABEL TEXT**

**[Adult Fleas]**

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Starts killing fleas within 30 minutes\* (mins)

\*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

**[Flea Eggs]**

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (dog *or* puppy *or* dog and puppy) that live in your home

Kills flea eggs on your (dog *or* puppy *or* dog and puppy) to prevent the eggs from hatching in your home.

**[Ticks]**

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

**April 3, 2014**

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

**April 3, 2014**

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Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)  
Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills flea eggs and flea larvae to help prevent future re-infestations  
Kills all stages of the flea life cycle  
Breaks the flea life cycle  
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.  
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)  
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations  
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)  
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)  
Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)  
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)  
Stays on and doesn't rub off  
Kills fleas for 30 days (1 month) (4 weeks)  
Stops and prevents infestations  
Prevents re-infestation  
Prevents and controls re-infestation(s)  
Dual insect growth regulator (IGR) prevents re-infestation  
Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas  
Fast acting  
Long lasting  
Effective and convenient topical treatment  
Kills fleas (and ticks) through (after) contact  
(With) patented applicator  
Waterproof  
Effective after bathing  
Effective after exposure to water  
Easy spot on topical applicator  
Patents Pending

April 3, 2014

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Do not reapply product for 30 days  
Remains effective even after bathing, water immersion, or exposure to sunlight  
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.  
Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Fast Acting**
- **Long Lasting**
- **Waterproof**

Only for dogs and puppies 8 weeks of age or older

Specially formulated for dogs and puppies 8 weeks of age or older

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

**April 3, 2014**

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To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_

Second Dose \_\_\_\_\_

Third Dose \_\_\_\_\_

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

*Providing Leadership in Environmental Entomology*

Department of Entomology, Soils, and Plant Sciences • 114 Long Hall • Clemson, SC 29634-0315 • Phone: 864-656-3111  
email: dpento@clemson.edu

### TICKS AROUND YOUR HOME

Ticks are closely related to scorpions, spiders and mites. They are not insects. They are external parasites that need a blood meal to survive and reproduce. Ticks can feed on humans and other mammals, reptiles, birds or even frogs. All life stages of ticks feed on blood. Ticks can transmit several diseases, such as Lyme disease, rocky mountain spotted fever, tick paralysis, and others, but most tick bites do not result in illness.

**Life Cycle.** Ticks have a simple life cycle. Eggs hatch into six-legged larvae, an immature stage. Depending on the kind of tick, the larva can be extremely active or lay in wait for a host to come. Once on the host, the larva will begin feeding. After the tick is full of blood, it will either fall off the host or stay on, depending on the type of tick. The next step for the tick is to turn into a nymph. From this point on, the tick will have eight legs. Some ticks go through many nymphal stages, while some only have one. The nymph will have a blood meal at every stage. After the nymph goes through all of its stages, it will turn into an adult. The adult will either stay on the original host, or find a new one if the nymph dropped off after feeding.

**Types of Ticks.** There are about 80 different kinds of ticks in the United States. Most of them are not associated with humans or their pets. The information presented here will help you understand what to do if you encounter one of the wood ticks or the brown dog tick in or around your home.



Deer Tick

Photo Source: Iowa State Univ.

**Wood ticks.** The name wood tick is used for many ticks including the blacklegged or deer tick, lone star tick and American dog tick. These are usually found in woodland areas. If a home is built in an

area that was recently a field or forest, there is a higher chance that these ticks will be close-by. They crawl around for several hours often before attaching themselves to a host, so they may be accidentally brought into a home on pets or clothing. Wood ticks do not establish populations indoors.

**Brown dog tick.** The brown dog tick can be a nuisance in the home. It is one of only a few ticks that will infest a structure. The brown dog tick prefers to feed on dogs, but will occasionally feed on other hosts, such as humans.



Brown Dog Tick

They usually are found only where dogs occur. They can be picked up in such common places as infested homes, kennels, veterinarian's office, or outdoor areas frequented by an infested animal. On the animal, the larval and nymphal stages of the tick are normally found in the long hair along the back of a dog. The adult stage is found in the ear or between the toes. When an infestation occurs indoors, ticks will be found in cracks, crevices, behind baseboards and in other protected places close to the floor. Since the brown dog tick and adult female can lay as many as 5,000 eggs, the infestation can be very large.

**Prevention is the Key to Control.** The best way to avoid tick bites and the diseases they may carry is to avoid ticks. The best way to do that is to avoid places where ticks live, such as wooded areas. That is not always possible, but precautions can be taken. Long-sleeved shirts, long pants and hats should be worn when in tick-infested areas. Ticks are easier to detect when you wear light-colored clothes. To prevent ticks from getting under plants, you should tuck cuffs into the

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Public Service Activities

socks or shoes. Tuck long hair under a hat. Also, tick repellent can be applied to the outside of clothes, especially the pants.

Do visual inspection of your clothes and body twice a day when in tick-infested areas. The larvae and nymphs of ticks are quite small and can be easily mistaken for freckles or dirt. Ticks like to feed on the back of the head at the base of the skull. It is a good idea to have another person check for ticks in places you cannot easily see. All clothing should be washed in warm water and detergent. If your pets accompany you to the woods, check them too.

**Non-chemical Control.** If you are having problems with rodents or other wild animals, such as raccoons or opossums, take measures to exclude them from your house or yard. Also, keep shrubs trimmed along the paths near your home. Keep grass mowed, and remove weeds, brush and leaf litter close to your house to reduce tick problems.

**Chemical Control.** Indoor chemical control of ticks is usually not recommended except for brown dog tick. Other ticks will not establish inside. In the case of the brown dog tick, applications should be limited to crack and crevice treatments, and areas where the animal spends the most time. Animal bedding or sleeping areas should receive special attention. Brown dog ticks will not be found in high places. Think about the brown dog tick as being at the level of the dog. You can use many of the same spray or dust products you would use for cockroach control to control brown dog ticks. Check the label for product that can be used in the same sites as those you need to treat. Always read and follow label instructions. At the same time that the home is treated for brown dog tick, also treat the animal with an approved product.

Outdoor treatments for any type of tick should be limited to those areas where pets spend the most time. Crawlspace, outdoor walls, cracks and crevices should only be treated if ticks are observed in these places. General treatments for ticks are not

recommended because they often are not very effective. Removal of tick habitats is much more helpful.

If you have a severe infestation in or around your home you may want to hire a professional pest control company to control your tick problem. Professionals can safely use products that are not available to consumers.

**Tick Bites.** As mentioned earlier, some ticks may transmit diseases. If a tick bites you, there are a few things that you should do. First, carefully remove the tick by grasping it with a pair of tweezers at the point closest to the skin. Pull it out slowly and steadily. After the tick is removed, disinfect the bite area. Also, make sure that you don't crush the tick because if the tick is infected, crushing it could introduce the disease into your body. Save the tick by placing it in a small container with rubbing alcohol. This way if you suspect a tick-related problem later on, the tick can be identified. Although, keep in mind, that to test the tick for disease, it must be kept alive. Finally, record the date on your calendar that you were bitten just in case symptoms appear later.

*For other publications in our Entomology Insect Information Series visit our web site at <http://www.clemson.edu/esps>.*

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Prepared by Jonathan M. Sargent, Graduate Extension Assistant, Patricia Zungoli, Extension Entomologist/Professor, and Eric P. Benson, Extension Entomologist/Associate Professor, Department of Entomology, Soils, and Plant Sciences, Clemson University.

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This information is supplied with the understanding that no discrimination is intended and no endorsement by the Clemson University Cooperative Extension Service is implied. Brand names of pesticides are given as a convenience and are neither an endorsement nor guarantee of the product nor a suggestion that similar products are not effective. Use pesticides only according to the directions on the label. Follow all directions, precautions and restrictions that are listed.  
EHS/MV-5 (New 10/1998).



## Rodia, Carmen

---

**From:** Rodia, Carmen  
**Sent:** Wednesday, April 02, 2014 4:24 PM  
**To:** DJones@hartz.com  
**Cc:** McCall, Deborah; Gebken, Richard; Petrella, Carlyn  
**Subject:** FINAL Label Review Comments for EPA File Symbol 2596-RTI (Hartz Reference #143)  
**Attachments:** 2596-178 (Hartz Reference #143), E-Copy of Marked Up Label (04-02-14).pdf

David, in a FINAL attempt to obtain from The Hartz Mountain Company a "clean label" with no comments that can be used to out-process the STILL pending/EXPEDITED R315 new product registration for EPA File Symbol 2596-RTI (Hartz Reference #143), I have attached a FINAL "marked up" copy of the updated master label as well as a list of what we are calling our FINAL label review comments. This FINAL list of label review comments included changes necessary as part of the Agency's PERC committee meeting on April 1, 2014. As such, my FINAL label review comments are as follows:

Pet Spot-On Mitigation Statement subsection comment(s), bottom of page 3 of 10:

1. Since the subject product contains fipronil, you must insert the word "immediately" at the very end of the 3<sup>rd</sup> sentence within this subsection.

OPTIONAL/ALTERNATE LABEL TEXT section comment(s), page 6-8 of 10:

2. You must delete all text within this section that has been marked with "strikethrough."
3. Within the "[Tick]" subsection in the middle of page 7 of 10, you must delete the word "larvae" since the tick life cycle does not include a larval life stage.

As such, you must submit a further amended master label which incorporates all of the remaining FINAL label review comments. If you have any questions, please call me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.  
Environmental Protection Specialist  
U.S. EPA, Office of Pesticide Programs,  
Registration Division, Insecticide Branch  
1200 Pennsylvania Avenue, NW (7504P)  
Washington, DC 20460-0001  
(703) 306-0327 (tel)  
(703) 308-0029 (fax)  
[Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov)

April 2, 2014

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## Hartz® Reference # 143

### Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

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FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

### **FRONT PANEL**

#### **ACTIVE INGREDIENTS:**

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
<b>OTHER INGREDIENTS .....</b>	<b>81.15%</b>
<b>TOTAL .....</b>	<b>100.00%</b>

#### **KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See back panel for additional precautionary statements.

#### **NET CONTENTS:**

April 2, 2014

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



(1.5 x 1.5 cm icon)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]

DO NOT USE ON CATS

## **BACK PANEL**

### **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

### **HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

### **PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

April 2, 2014

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#### FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

#### READ ENTIRE LABEL BEFORE EACH USE

**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**

**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**

**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**

**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**

**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



(Place in a 1.5 x 1.5 cm yellow box with black images only.)

**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

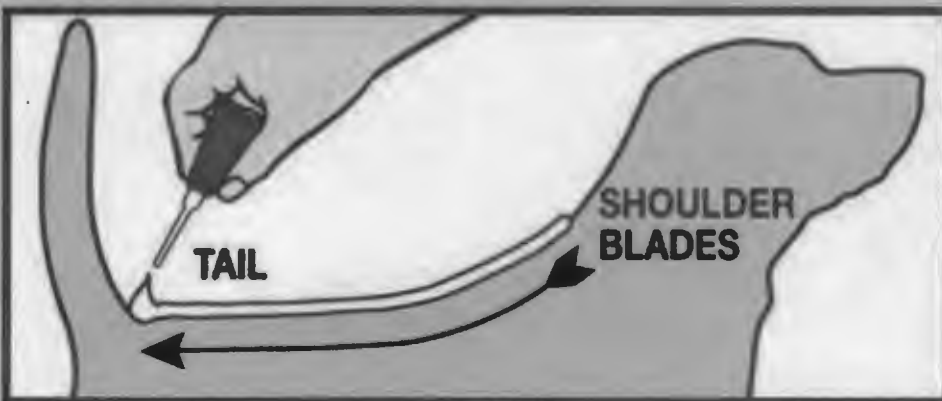
April 2, 2014



**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.

April 2, 2014

#### **SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

#### **INDIVIDUAL TUBE TEXT**

*[Product name]*

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

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**OPTIONAL/ALTERNATE LABEL TEXT**

[Adult Fleas]

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

~~Prevents flea infestation of your pet and your home.~~

~~Prevents flea infestation of your pet and your home.~~

~~Prevents flea infestation of your pet and your home.~~

Starts killing fleas within 30 minutes\* (mins) \*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (dog or puppy or dog and puppy) that live in your home

Kills flea eggs on your (dog or puppy or dog and puppy) to prevent the eggs from hatching in your home.

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

[illegible]



**April 2, 2014**

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs ~~ticks~~

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

April 2, 2014

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) ~~technology~~ prevents re-infestation

~~Dual insect growth regulator (IGR) technology prevents re-infestation~~

Contains two ~~active~~ ingredients to prevent flea infestations

~~Contains two active ingredients to prevent flea infestations~~

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator



April 2, 2014

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Waterproof  
Effective after bathing  
Effective after exposure to water  
Easy spot on topical applicator  
Patents Pending

Do not reapply product for 30 days  
Remains effective even after bathing, water immersion, or exposure to sunlight  
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.  
Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Fast Acting**
- **Long Lasting**
- **Waterproof**

Only for dogs and puppies 8 weeks of age or older

Specially formulated for dogs and puppies 8 weeks of age or older

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

•Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

**April 2, 2014**

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You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_

Second Dose \_\_\_\_\_

Third Dose \_\_\_\_\_

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

Decision Seq: 483630 Action Code: **R315, NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUB**FFS Start Date: 22-Oct-2013 Tentative Ind: No  FQPA Clock:

Due Date: 22-Jul-2014 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 22-Oct-2013 FFS Original Decision:

Negotiated Due Date: 90-Day Due Date: 21-Jan-2014

Registrant  Predecisional Due Date: 08-Jul-2014 Add to Bundle? ☐

Response Due Date:

Current Status: PENDING (02-Apr-2014)

Bundle ID:

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Decision Bundle

  Primary Decisions Decision Milestone         

Receipts	Staff Member	Reg/DC Number	Submission Due Date	Receipt
<input type="button" value="..."/> S:949007	Petrella, Carlyn	<input type="button" value="..."/> 2596-RTI	22-Jul-2014	PENDING
Submission of further updated master label.				
<input type="button" value="..."/> S:949402	Petrella, Carlyn	<input type="button" value="..."/> 2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of updated master label.				
<input type="button" value="..."/> S:946769	Petrella, Carlyn	<input type="button" value="..."/> 2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT
Submission of additional information per 75 day deficiency letter.				
<input type="button" value="..."/> S:941688	Petrella, Carlyn	<input type="button" value="..."/> 2596-RTI	22-Jul-2014	SUPERSEDED BY NEW RECEIPT

Viewing Record 1 of 1

## Rodia, Carmen

---

**From:** DJones@hartz.com  
**Sent:** Wednesday, April 02, 2014 12:19 PM  
**To:** Rodia, Carmen  
**Cc:** Petrella, Carlyn  
**Subject:** EPA File No. 2596-RTI; 2014 Apr 2 Hartz Ref 143 Master lbl.pdf, 2014 Apr 2 Hartz Ref 143 Strike out hilight version Master lbl.doc  
**Attachments:** 2014 Apr 2 Hartz Ref 143 Master lbl.pdf; 2014 Apr 2 Hartz Ref 143 Strike out hilight version Master lbl.doc

Carmen,

Per the discussion yesterday, attached is the new master label incorporating all remaining comments from the agency. I have attached two file versions, a strikeout version with additions in blue lettering in Word and the corresponding pdf accepting all of those edits without the edit marks.

Thank you again for the prompt response in helping us gain this registration. The related cat label will be following shortly in a separate e-mail.

Sincerely,

David Jones  
Manager Regulatory Affairs  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094  
TEL: 201-271-4800 x 7414  
FAX: 201-271-0357

:  
2014 Apr 2 Hartz Ref 143 Master lbl.pdf  
2014 Apr 2 Hartz Ref 143 Strike out hilight version Master lbl.doc

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

Hartz® Reference #143  
EPA Reg. No.: 2596-  
MASTER LABEL- -

March 21 April 2, 2014

## Hartz® Reference # 143

### Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
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### FRONT PANEL

#### ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS .....	<u>81.15%</u>
TOTAL .....	100.00%

#### KEEP OUT OF REACH OF CHILDREN

**CAUTION:** See back panel for additional precautionary statements.

#### NET CONTENTS:



Hartz® Reference #143  
EPA Reg. No.: 2596-  
MASTER LABEL -

March 21 April 2, 2014

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
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45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



(1.5 x 1.5 cm icon)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]

DO NOT USE ON CATS

#### **BACK PANEL**

##### **PRECAUTIONARY STATEMENTS**

##### **HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

##### **HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

##### **PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

Hartz® Reference #143  
EPA Reg. No.: 2596-  
MASTER LABEL -

~~March 21~~ April 2, 2014

#### FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

#### READ ENTIRE LABEL BEFORE EACH USE

**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**

**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**

**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**

**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**

**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



(Place in a 1.5 x 1.5 cm yellow box with black images only.)

**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

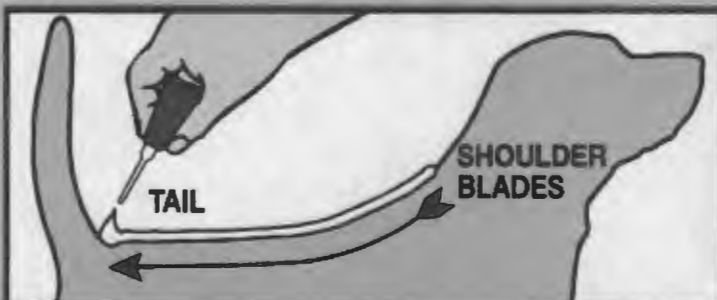
March 21, April 2, 2014



**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.

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#### **SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

#### **INDIVIDUAL TUBE TEXT**

*[Product name]*

For use **ONLY** on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

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**OPTIONAL/ALTERNATE LABEL TEXT**

[Adult Fleas]

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

~~Kills (Adult) Fleas (for up to 3 months)~~

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home environment

~~Prevents establishment of new infestations after application on premises~~

Prevents establishment of new infestations in the home environment

~~Prevents establishment of new infestations on premises~~

Starts killing fleas within 30 minutes\* (mins) ~~(and lasts for 30 days) (1 month) (4 weeks)~~

\*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (dog or puppy or dog and puppy) that live in your home

Kills flea eggs on your (dog or puppy or dog and puppy) to prevent the eggs from hatching in your home.

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March 21 April 2, 2014

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older  
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older  
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older  
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks  
Kills adult (brown dog) (deer) ticks, nymphs and larvae  
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations  
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice  
Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

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Kills ~~adult Fleas,~~ Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home ~~environment~~ (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults ~~on-premises~~ (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation

Dual insect growth regulator (IGR) technology prevents re-infestation in the home ~~environment~~

~~Dual insect growth regulator (IGR) technology prevents re-infestation on premises~~

Contains two unique ingredients to prevent flea infestations

Contains two unique ingredients to prevent flea infestations in the home ~~environment~~

~~Contains two unique ingredients to prevent flea infestations on premises~~



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Rapidly eliminates fleas  
Fast acting  
Long lasting  
Effective and convenient topical treatment  
Kills fleas (and ticks) through (after) contact  
(With) patented applicator  
Waterproof  
Effective after bathing  
Effective after exposure to water  
Easy spot on topical applicator  
Patents Pending

Do not reapply product for 30 days  
Remains effective even after bathing, water immersion, or exposure to sunlight  
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.  
Avoid contact with treated area until dry.  
Convenient to use  
Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.  
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)  
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)  
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Kill(s) Fast Acting
- Repels(s) Long Lasting
- Prevent(s) Waterproof

New (Formula) ~~(claim to be removed 6 months after date product is first sold or distributed)~~

Only for dogs and puppies 8 weeks of age or older  
Specially formulated for dogs and puppies 8 weeks of age or older

#### **NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose  
First month, second month, third month  
Value pack  
3 month supply  
3 monthly treatment(s)  
Apply monthly (every 30 days)  
Convenient (easy to use) applicator  
(3) Pro-cision Flo® Applicator(s) (included)  
(Pro-cision Flo® Applicator)

Optional/alternate text in parentheses or brackets

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Featuring Pro-cision Flo® Applicator (for easy application)  
Direct to your dog's skin  
Easy (simple) to use (handle) (apply)  
Made in the U.S.A  
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours  
You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_  
Second Dose \_\_\_\_\_  
Third Dose \_\_\_\_\_

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

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EPA Est. No. 2596-OH-1

April 2, 2014

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## Hartz® Reference # 143

### Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)  
First Defense Pro™ for Dogs (&) (and Puppies)  
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

### FRONT PANEL

#### ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%

OTHER INGREDIENTS .....	81.15%
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TOTAL .....	100.00%
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#### KEEP OUT OF REACH OF CHILDREN

**CAUTION:** See back panel for additional precautionary statements.

#### NET CONTENTS:

April 2, 2014

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



(1.5 x 1.5 cm icon)

*[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]*

**DO NOT USE ON CATS**

## **BACK PANEL**

### **PRECAUTIONARY STATEMENTS**

#### **HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

#### **HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

### **PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

April 2, 2014

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### FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

### READ ENTIRE LABEL BEFORE EACH USE

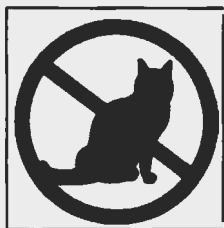
**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**

**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**

**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**

**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**

**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



(Place in a 1.5 x 1.5 cm yellow box with black images only.)

**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

April 2, 2014



**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.

April 2, 2014

#### **SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

#### **INDIVIDUAL TUBE TEXT**

*[Product name]*

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

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**OPTIONAL/ALTERNATE LABEL TEXT**

[Adult Fleas]

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home

Prevents establishment of new infestations in the home

Starts killing fleas within 30 minutes\* (mins) \*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (dog or puppy or dog and puppy) that live in your home

Kills flea eggs on your (dog or puppy or dog and puppy) to prevent the eggs from hatching in your home.

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

**April 2, 2014**

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)



**April 2, 2014**

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Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation

Dual insect growth regulator (IGR) technology prevents re-infestation in the home

Contains two unique ingredients to prevent flea infestations

Contains two unique ingredients to prevent flea infestations in the home

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

April 2, 2014

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Waterproof

Effective after bathing

Effective after exposure to water

Easy spot on topical applicator

Patents Pending

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Fast Acting**
- **Long Lasting**
- **Waterproof**

Only for dogs and puppies 8 weeks of age or older

Specially formulated for dogs and puppies 8 weeks of age or older

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

**April 2, 2014**

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You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_

Second Dose \_\_\_\_\_

Third Dose \_\_\_\_\_

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

## Rodia, Carmen

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**From:** DJones@hartz.com  
**Sent:** Saturday, March 22, 2014 1:54 PM  
**To:** Rodia, Carmen  
**Cc:** Petrella, Carolyn; SMcNear@hartz.com  
**Subject:** EPA File Symbol 2596-RTI; 2014 Mar 21 Hartz Ref 143 Master lbl.doc  
**Attachments:** 2014 Mar 21 Hartz Ref 143 Master lbl.pdf

Dear Carmen,

Yesterday I called to discuss these labels about 20 minutes after the Hartz Reference No. 142 teleconference was originally scheduled to conclude. I left a voice mail message at 2:20 pm. As indicated in that message I have attached the modified label. It responds to the complete set of comments provided in the e-mail sent to Hartz on March 18. Many edits were implemented. For the edits we modified, supporting references ranging from PR Notices, recent stamped accepted labels, the Pet Spot-On mitigation letter and other citations are offered in support of the text. To aid in reviewing the attached label we offer the following comments. They align to the e-mail comment numbers as presented in the March 18, 2014 e-mail:

### 1. General Statements - EPA Strikeouts on label

- Page 5 - deleted hotline sentence from the label
- Page 6 - 3 months - 3 month duration claims retained. The recently stamped accepted master labels for Hartz EPA Reg. No. 2596-165 (top of page 6, middle page 7) bear these claims based on identical data and claims on the related precedent label for the original data submitter. Our comparable label was very recently stamped accepted with the 3 month duration claims.
- Pages 6 and 8 - "home environment" and "premises" portion of claims. The EPA master stamped February 26, 2014 contains these claims (top of page 6, middle of page 8). The life cycle disruption data cited has and does support these claims.
- Page 7 - Adult tick "larvae" - According to our entomologist, the data supports the tick larvicidal claim. The EPA master stamped February 26, 2014 for EPA Reg. No. 2596-165, has this claim at the top of page 7.
- Page 9 - Triple "Action" - To clearly define the three actions we have added "kills", "repels" and "prevents".

2. Pet Spot On Mitigation Warnings (Front Panel) - The warning statements section on page 1 was deleted. The phrases specified were on page 2 (now at the top of page 2). The words "and puppies" are added to meet the mitigation requirement.

3. and 4. - Pet Spot on Mitigation Statement - The icon color, size and background text are incorporated. Per the mitigation policy only the phrase "DO NOT USE ON CATS" appears by the icon on the front panel. The appropriate statement will appear on the back panel by the icon as per the mitigation requirements.

5. and 6. Precautionary Statements - Label incorporates all changes stipulated.

7. and 8. Pet Spot on Mitigation Icon and warning - Icon color, format and background changes all implemented. The warning statement was included as per the mitigation policy. The last word "immediately" is not included as it is required for the products containing phenothrin, permethrin and cyphenothrin. This product has none of those compounds.

9. Storage and Disposal - Language implemented in label as specified.

10. Pet Spot on Mitigation Warnings, Tube -The label incorporates the language specified. In addition we added "and puppies" per the related mitigation letter.

11. Option/Alternate Label Text - The 30 minute speed of kill claim in the attached label is consistent with the Feb. 26, 2014 stamped label accepted under EPA Reg. No 2596-165. For consistency Hartz has also added label formatting text specifying proximity and sizing of the claim text. The data supporting 2596-165 and this product are identical. MRIDs 49153901, 49151201 and 49115704 are based on the same Bertek, Inc. Lab Project No. 2563. With the formulation difference being the addition of 0.25% pyriproxyfen, Hartz is relying on the agency to support a consistent conclusion for identical data supporting this speed of kill claim. The second bullet, add "[Flea Eggs]" was added per the e-mail.

12. Optional/Alternate Label Text "New" - The phrase after the word "New" has been modified to be consistent with PR Notice 98-10 K.5. As this registration will be a new formula for Hartz with the addition of pyriproxyfen we contend it meets K.5. which allows "new" "...for a period of six months after EPA's approval of a revised or alternate formula and beginning when the product with this claim is first sold or distributed." This supports the new qualifying phrase of "*(claim to be removed 6 months after date product is first sold or distributed)*".

I had hoped to discuss the issues but realizing the time is short, this label and above discussion are offered to facilitate a

rapid conclusion. Please let me know if I can provide further support or information. Thank you for all your efforts in this application.

Sincerely,

David Jones

Manager Regulatory Affairs

The Hartz Mountain Corporation

400 Plaza Drive

Secaucus, NJ 07094

TEL: 201-271-4800 x 7414

FAX: 201-271-0357

March 21, 2014

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## Hartz® Reference # 143

### Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)  
First Defense Pro™ for Dogs (&) (and Puppies)  
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

### FRONT PANEL

#### ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
<b>OTHER INGREDIENTS .....</b>	<b>81.15%</b>
<b>TOTAL .....</b>	<b>100.00%</b>

#### KEEP OUT OF REACH OF CHILDREN

**CAUTION:** See back panel for additional precautionary statements.

#### NET CONTENTS:

March 21, 2014

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



(1.5 x 1.5 cm icon)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]

DO NOT USE ON CATS

## **BACK PANEL**

### **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

### **HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

### **PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

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#### FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

#### READ ENTIRE LABEL BEFORE EACH USE

**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**  
**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**  
**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**  
**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**  
**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



(Place in a 1.5 x 1.5 cm yellow box with black images only.)

**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

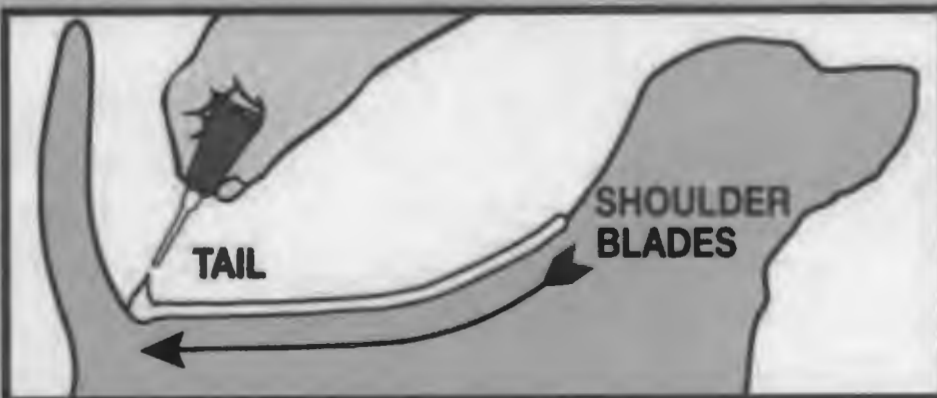




**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.

#### **SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

#### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

#### **INDIVIDUAL TUBE TEXT**

*[Product name]*

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

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**OPTIONAL/ALTERNATE LABEL TEXT**

[Adult Fleas]

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home environment

Prevents establishment of new infestations after application on premises

Prevents establishment of new infestations in the home environment

Prevents establishment of new infestations on premises

Starts killing fleas within 30 minutes\* (mins) (and lasts for 30 days) (1 month) (4 weeks)

\*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

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Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older  
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older  
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older  
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks  
Kills adult (brown dog) (deer) ticks, nymphs and larvae  
Kills Ticks including those that may transmit Lyme disease

**[Lice & Mange]**

Rapidly eliminates chewing lice infestations  
Aids in Control of sarcoptic mange infestations

**[Multiple]**

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice  
Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.  
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

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Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults on premises (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation

Dual insect growth regulator (IGR) technology prevents re-infestation in the home environment

Dual insect growth regulator (IGR) technology prevents re-infestation on premises

Contains two unique ingredients to prevent flea infestations

Contains two unique ingredients to prevent flea infestations in the home environment

Contains two unique ingredients to prevent flea infestations on premises

Rapidly eliminates fleas

Fast acting

March 21, 2014

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Long lasting  
Effective and convenient topical treatment  
Kills fleas (and ticks) through (after) contact  
(With) patented applicator  
Waterproof  
Effective after bathing  
Effective after exposure to water  
Easy spot on topical applicator  
Patents Pending

Do not reapply product for 30 days  
Remains effective even after bathing, water immersion, or exposure to sunlight  
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.  
Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Kill(s)**
- **Repels(s)**
- **Prevent(s)**

New (Formula) (*claim to be removed 6 months after date product is first sold or distributed*)

Only for dogs and puppies 8 weeks of age or older

Specially formulated for dogs and puppies 8 weeks of age or older

#### **NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

---

Easy (simple) to use (handle) (apply)  
Made in the U.S.A  
Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours  
You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_  
Second Dose \_\_\_\_\_  
Third Dose \_\_\_\_\_

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

## Rodia, Carmen

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**From:** Rodia, Carmen  
**Sent:** Tuesday, March 18, 2014 3:35 PM  
**To:** DJones@hartz.com  
**Cc:** McCall, Deborah; Gebken, Richard; Petrella, Carlyn; SMcNear@hartz.com  
**Subject:** FINAL Label Review Comments for EPA File Symbol 2596-RTO (Hartz Reference #144)  
**Attachments:** 2596-RTI -RTO, Efficacy Review (03-18-14).pdf; 2596-RTO (Harts Reference #144), E-Copy of Marked Up Label (03-18-14).pdf

David, in anticipation of stamping a "clean label" with no comments in support of the pending R315 new product registration for EPA File Symbol 2596-RTO (Hartz Reference #144), I have attached a revised "marked up" copy of the proposed master label as well as a list of FINAL label review comments that will need to be incorporated into an amended master label for out-processing this EXPEDITED new product application. This FINAL list of label review comments included changes necessary as part of the completed efficacy review (copy attached). As such, my FINAL label review comments are as follows:

General Statement(s):

1. Delete all text throughout the subject label that is marked with "strikethrough."

Pet Spot-On Mitigation Warning Statement section comment(s), bottom of page 1 of 9:

2. In order to address label clarity, you must revise the last text statement at the bottom of page 1 of 9 to read "For use **ONLY** on cats & kittens 8 weeks and older, weighing 3 lbs. or more."

Precautionary Statements, Hazards to Humans subsection comment(s), top of page 2 of 9:

3. To facilitate inclusion of required label changes from the similarity clinic memo completed in support of this new product registration, you must revise this subsection to read "Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet."

Precautionary Statements, First Aid subsection comment(s), middle of page 2 of 9:

4. In order to maintain consistency with other Hartz products, you must revise the 2<sup>nd</sup> sentence within the existing "**HOT LINE NUMBER**" subsection to read "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week."

Storage and Disposal section comment(s), middle of page 4 of 9:

5. In order to maintain consistency with the product chemistry review that completed in support of this pending application for registration as well as the "**Physical or Chemical Hazards**" subsection at the top of page 2 of 9, you must insert the following text immediately following the existing 1<sup>st</sup> sentence to read "Do not use or store near heat or open flame."

Optional/Alternate Label Text section comment(s), middle of page 6 of 9:

6. In order to maintain consistency with the efficacy review that completed in support of this pending application for registration, you may add the following text immediately following the 1<sup>st</sup> proposed optional marketing claim within the "[Flea Eggs]" subsection to read "(3 months)"

Optional/Alternate Label Text section comment(s), middle of page 8 of 9:

7. In order to maintain consistency with the draft Notice of Registration for this pending new product, revise the existing optional/alternate marketing claim "New (Formula) (***claim to be removed after 6 months***)" to read "New (Formula) (***claim to be removed 6 months following registration of this product***)"

As such, you must submit an amended master label which incorporates all of the above FINAL label review comments. If you have any questions, please call me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.



Environmental Protection Specialist  
U.S. EPA, Office of Pesticide Programs,  
Registration Division, Insecticide Branch  
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**Hartz® Reference # 144**Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)  
 Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)  
 Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)  
 Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)  
 Hartz® FieldForce Pro™ for Cats (& Kittens)  
 Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)  
 Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)  
 Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)  
 Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)  
 First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)  
 First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)  
 First Defense Pro™ for Cats (& Kittens)  
 FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)  
 First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)  
 First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL**ACTIVE INGREDIENTS:**

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
<b>OTHER INGREDIENTS .....</b>	<b>78.15%</b>
<b>TOTAL .....</b>	<b>100.00%</b>

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See back panel for additional precautionary statements.

**NET CONTENTS:** 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 Weeks and older weighing 3lbs. or more.

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**BACK LABEL**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

**PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

**FIRST AID**

Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS.

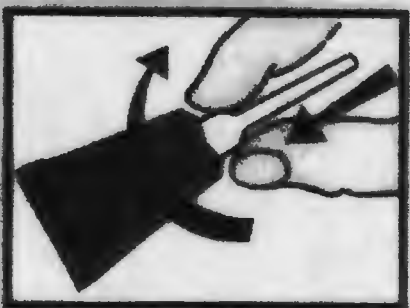
DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:

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**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat once a month.

#### **SIDE EFFECTS**

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

### **FREQUENCY OF APPLICATION**

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

~~For information, call 1-800-233-2444 (toll-free) or 201-261-1000 (NJ only).~~  
~~© 2011~~

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

### **INDIVIDUAL TUBE TEXT**

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

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**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See full label for additional directions

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**OPTIONAL/ALTERNATE LABEL TEXT**

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

**[Adult Fleas]**

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

~~Kills (Adult) Fleas (for up to 5 months)~~

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) ~~(2 months)~~

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) ~~(2 months)~~

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) ~~(2 months)~~

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) ~~(2 months)~~ on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) ~~(2 months)~~ on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) ~~(2 months)~~

~~(2 months)~~ on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs



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If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

~~Prevents establishment of new infestations after application in the home environment~~

~~Prevents establishment of new infestations after application on premises~~

~~Prevents establishment of new infestations in the home environment~~

~~Prevents establishment of new infestations in the home environment~~

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks  
(for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs ~~and larvae~~

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (on premises) (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

~~Prevents re-infestation~~

~~Prevents re-infestation~~

~~Dual insect growth regulator (IGR) technology prevents re-infestation~~

Dual insect growth regulator (IGR) technology prevents re-infestation

~~Dual insect growth regulator (IGR) technology prevents re-infestation~~

Contains two unique ingredients to prevent flea infestations

~~Contains two unique ingredients to prevent flea infestations~~



~~Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®).~~  
Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Effective after bathing

Effective after exposure to water

Patents Pending

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

~~Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)~~

New (Formula) (*claim to be removed after 6 months*)

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more

Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

With Pro-cision Flo® Applicator

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Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_

Second Dose \_\_\_\_\_

Third Dose \_\_\_\_\_

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

Nylar® - Registered Trademark of McGlaughlin Gormley King Company

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

## Rodia, Carmen

---

**From:** Rodia, Carmen  
**Sent:** Thursday, March 13, 2014 11:31 AM  
**To:** DJones@hartz.com  
**Cc:** McCall, Deborah; Gebken, Richard  
**Subject:** Preliminary Label Review Comments for EPA File Symbol 2596-RTI (Hartz Reference #143)  
**Attachments:** 2596-RTI (Hartz Reference #143), E-Copy of Marked Up Label (03-13-14).pdf

David, in anticipation of stamping a "clean label" with no comments in support of the pending R315 new product registration for EPA File Symbol 2596-RTI (Hartz Reference #143), I have attached a "marked up" copy of the proposed master label as well as a list of preliminary label review comments that will need to be incorporated into an amended master label for out-processing this new product application. The only remaining review that we are waiting for at this point is the efficacy review. Once the efficacy review has been completed, I might have a number of final comments that might need to be incorporated into an even further master label. As such, my preliminary label review comments are as follows:

General Statement(s):

1. Delete all text throughout the subject label that is marked with "strikethrough."

Pet Spot-On Mitigation Warning Statements (FRONT PANEL) section comment(s), bottom of page 1 of 10:

2. In order to address label clarity, you must revise the warning statements at the bottom of page 1 of 10 to read as follows:

"For use **ONLY** on dogs 8 weeks and older, weighing 5 to 22 lbs.  
For use **ONLY** on dogs 8 weeks and older, weighing 23 to 44 lbs.  
For use **ONLY** on dogs 8 weeks and older, weighing 45 to 88 lbs.  
For use **ONLY** on dogs 8 weeks and older, weighing 89 to 132 lbs."

Pet Spot-On Mitigation Statement subsection comment(s), middle of page 2 of 10:

3. The 1.5 cm x 1.5 cm cat prohibition icon must be placed in a yellow box with **black images only**. If the box itself is yellow, a yellow and black cat prohibition icon may blend into the box.
4. Since the subject product contains fipronil, the existing pet spot-on mitigation statement "DO NOT USE ON CATS" listed at the middle left-hand side of page 2 of 10 is not complete. You must revise this pet spot-on mitigation statement to read as follows:

**"DO NOT USE ON CATS**  
Keep cats away from treated dogs for  
24 hours. If applied to or ingested by a cat, contact  
your veterinarian immediately."

Precautionary Statements, Hazards to Humans subsection comment(s), bottom of page 2 of 10:

5. To facilitate inclusion of required label changes from the similarity clinic memo completed in support of this new product registration, you must revise this subsection to read "Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet."

Precautionary Statements, First Aid subsection comment(s), top of page 3 of 10:

6. In order to maintain consistency with other Hartz products, you must revise the 2<sup>nd</sup> sentence within the existing "**HOT LINE NUMBER**" subsection to read "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week."

Pet Spot-On Mitigation Statement subsection comment(s), bottom of page 3 of 10:

7. The 1.5 cm x 1.5 cm cat prohibition icon must be placed in a yellow box with **black images only**. If the box itself is yellow, a yellow and black cat prohibition icon may blend into the box.

8. Since the subject product contains fipronil, the existing pet spot-on mitigation statement "DO NOT USE ON CATS" listed at the bottom left-hand side of page 3 of 10 is not complete. You must revise this pet spot-on mitigation statement to read as follows:

**"DO NOT USE ON CATS**  
Keep cats away from treated dogs for  
24 hours. If applied to or ingested by a cat, contact  
your veterinarian immediately."

Storage and Disposal section comment(s), top of page 5 of 10:

9. In order to maintain consistency with the product chemistry review that completed in support of this pending application for registration as well as the "**Physical or Chemical Hazards**" subsection at the bottom of page 2 of 10, you must insert the following text immediately following the existing 1<sup>st</sup> sentence to read "Do not use or store near heat or open flame."

Pet Spot-On Mitigation Warning Statements (TUBE TEXT) section comment(s), bottom of page 5 of 10:

10. In order to address label clarity, you must revise the warning statements at the bottom of page 5 of 10 to read as follows:

"For use **ONLY** on dogs weighing 5 to 22 lbs. – 0.023 fl. oz. (0.67 ml.)  
For use **ONLY** on dogs weighing 23 to 44 lbs. – 0.045 fl. oz. (1.34 ml.)  
For use **ONLY** on dogs weighing 45 to 88 lbs. – 0.091 fl. oz. (2.68 ml.)  
For use **ONLY** on dogs weighing 89 to 132 lbs. – 0.136 fl. oz. (4.02 ml.)"

Optional/Alternate Label Text section comment(s), middle of page 9 of 10:

11. In order to maintain consistency with the draft Notice of Registration for this pending new product, revise the existing optional/alternate marketing claim "New (Formula) (***claim to be removed after 6 months***)" to read "New (Formula) (***claim to be removed 6 months following registration of this product***)"

As such, you must submit an amended master label which incorporates all of the above preliminary label review comments. If you have any questions, please call me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.  
Environmental Protection Specialist  
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Registration Division, Insecticide Branch  
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(703) 308-0029 (fax)  
[Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov)

**Hartz® Reference # 143**Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)  
 Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)  
 First Defense Pro™ for Dogs (&) (and Puppies)  
 FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

**FRONT PANEL**

*[Each of the above brands will be packaged in the weight classes designated below:]*

Weighing 5 to 22 lbs.  
 Weighing 23 to 44 lbs.  
 Weighing 45 to 88 lbs.  
 Weighing 89 - 132 lbs.

**ACTIVE INGREDIENTS:**

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
<b>OTHER INGREDIENTS .....</b>	<b>81.15%</b>
<b>TOTAL .....</b>	<b>100.00%</b>

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See back panel for additional precautionary statements.

**NET CONTENTS:**

<b>For use ONLY on Dogs and Puppies 8 weeks and older Weighing:</b>	<b>Net Contents (Each tube)</b>
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



*[Cat Warning: A cat prohibition icon will appear on the front panel and back panel.]*

**DO NOT USE ON CATS**

**BACK PANEL**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

**PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

**FIRST AID**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and

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veterinary health concerns, emergency medical treatment information or pesticide incidents.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

**READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**

**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**

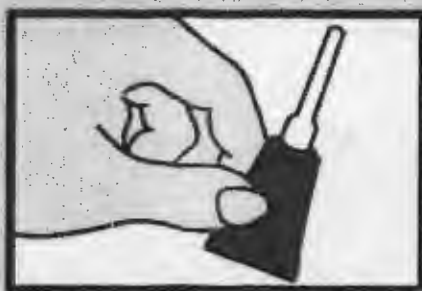
**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**

**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**

**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.



**SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

~~For more information call our (toll-free) experts at 1-800-275-1414 (ask for Dept. 5000) or visit us online at [www.hartz.com](http://www.hartz.com).~~

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

**INDIVIDUAL TUBE TEXT**

[Product name]

Only for use on DOGS AND PUPPIES 8 WEEKS OR OLDER

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

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**OPTIONAL/ALTERNATE LABEL TEXT**

[Adult Fleas]

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

~~Prevents establishment of flea infestations in the home~~

~~Prevents establishment of flea infestations in the home~~

~~Prevents establishment of flea infestations in the home~~

~~Prevents establishment of flea infestations in the home~~

~~Prevents establishment of flea infestations in the home~~

Starts killing fleas within 30 minutes (mins) (and lasts for 30 days) (1 month) (4 weeks)

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)  
Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults on premises (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation

~~Dual insect growth regulator (IGR) technology prevents re-infestation in the home environment~~

~~Dual insect growth regulator (IGR) technology prevents re-infestation on premises~~

Contains two unique ingredients to prevent flea infestations

~~Contains two unique ingredients to prevent flea infestations in the home environment~~

~~Contains two unique ingredients to prevent flea infestations on premises~~

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

Waterproof

Effective after bathing

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Effective after exposure to water  
Easy spot on topical applicator  
Patents Pending

Do not reapply product for 30 days  
Remains effective even after bathing, water immersion, or exposure to sunlight  
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.  
Avoid contact with treated area until dry.  
Convenient to use  
Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.  
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)  
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

~~Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)~~

New (Formula) (*claim to be removed after 6 months*)

Only for dogs and puppies 8 weeks of age or older  
Specially formulated for dogs and puppies 8 weeks of age or older

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_

Hartz® Reference #143

EPA Reg. No.: 2596-

MASTER LABEL- -

September 18, 2013

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Second Dose \_\_\_\_\_

Third Dose \_\_\_\_\_

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

**From:** Clayton Myers, Ph.D., Entomologist/Biologist

**Date:** March 18, 2014

**Subject:** PRODUCT PERFORMANCE DATA EVALUATION RECORD

**2596-RTI**

**DP barcode:** 417330

**Decision no.:** 483630

**Submission no:** 941688

**Action code:** R315

**Product Name:** Hartz Reference #143

**EPA Reg. No or File Symbol:** 2596-RTI

**Formulation Type:** Pet spot-on for dogs

**Ingredients statement from the label with PC codes included:** 9.80% fipronil (pc code 129121), 8.8% s-Methoprene (pc code 105402), and 0.25% Pyriproxyfen (pc code 129032).

**Application rate(s) of product:** Various, depending on pet weight class

**OCSP/OPPTS Guidelines:** OPPTS 810.3300.

**2596-RTO**

**DP barcode:** 417293

**Decision no.:** 483629

**Submission no:** 941691

**Action code:** R315

**Product Name:** Hartz Reference #144

**EPA Reg. No or File Symbol:** 2596-RTO

**Formulation Type:** Pet spot-on for cats

**Ingredients statement from the label with PC codes included:** 9.80% fipronil (pc code 129121), 11.8% s-Methoprene (pc code 105402), and 0.25% Pyriproxyfen (pc code 129032).

**Application rate(s) of product:** Various, depending on pet weight class

**OCSP/OPPTS Guidelines:** OPPTS 810.3300.

**I. Action Requested:** Review cited and submitted efficacy data to support the new product claims. Review labels.

## **II. Background:**

The registrant is citing Merial data and submitting speed of kill studies in support of new pet stripe-on products for dogs and cats with claims against ticks, fleas, etc.

## **III. Study Reviews:**

**Cited MRIDs:** 43577715, 43577716, 44942106, 45612701, 45618501, 45620501, 45620504, 45620505, 45620506, 45628101, 45628102, 45628103, 45628104, 45866901, 45866902, 46019201, 46019202,

The cited data included a number of titration, dosage, and efficacy studies for support of claims against fleas and ticks, etc. from Merial's database for the pioneer fipronil pet spot-on products. These studies are adequate to support killing and residual control claims against fleas, ticks, and other protection claims as listed on pioneer product labels, and as proposed on the submitted product labels. Speed of kill claims are not addressed by this cited data. No claims are supported beyond those approved for pioneer fipronil pet spot-on products.

**MRIDs 49115604 and 49115704 contain data for speed of kill adulticide claims against fleas that apply to both products cats and dogs, respectively**

**MRID 49115604. Everett, W.R. Speed of Kill Efficacy of a Dermal Treatment Applied to Cats Against Cat Fleas (*Ctenocephalides felis*). March 26, 2013.**

**Description:** This was a GLP study (with 2 noted exceptions) designed to evaluate the speed of kill of adult fleas for a stripe-on fipronil product applied at 0.50 ml test substance/test animal. Cats were ranked by flea retention and then randomly assigned to either a control or treatment group. 16 total cats, with weights varying from 6-13 lbs were used for the study. Speed of kill was assessed 2 days after application of treatments to animals. 100 fleas were placed on each cat, along the lateral mid-line of the animal. Flea removal was done with combs after each infestation at the various test times and mortality was assessed. Flea counts were log transformed and analyzed using a student's t-test. Mortality was calculated using Abbott's formula applied to geometric means.

**Results:** Control mortality exceeded 10 percent for every reading in the study, and was greater than 20% for the 15 minute reading. Mortality after 15 minutes was 0.0% and was not significantly different from the control. Mortality at 30 minutes was 3.4% and was not significantly different than the control. Mortality was 13.7% at 1 h and was not significantly different than the control. Mortality exceeded 25% at 2 hours, as the value was calculated to be 37.5%, which was significantly different than the control. However for this 2 h reading, control mortality was nearly 18%.



**Conclusion:** Due to insignificant mortality observations for most readings and excessive control mortality at the 2 hour reading, no speed of kill claims are supported for the cat product, 2596-RTO.

**MRID 49115704. Everett, W.R. Speed of Kill Efficacy of a Dermal Treatment Applied to Dogs Against Cat Fleas (*Ctenocephalides felis*). March 26, 2013.**

**Description:** This was a GLP study (with 2 noted exceptions) designed to evaluate the speed of kill of adult fleas for a stripe-on fipronil product applied at 0.030 ml test substance/lb test animal. Dogs were ranked by flea retention and then randomly assigned to either a control or treatment group. 16 total dog of mixed breed, with weights varying from 15-27 lbs were used for the study. Speed of kill was assessed 2 days after application of treatments to animals. 100 fleas were placed on each dog, along the lateral mid-line of the animal. Flea removal was done with combs after each infestation at the various test times and mortality was assessed. Flea counts were log transformed and analyzed using a student's t-test. Mortality was calculated using Abbott's formula applied to geometric means.

**Results:** Control mortality only exceeded 10 percent for the 48 hour reading, and was less than 15%. Mortality after 15 minutes was 3.1% and was not significantly different from the control. Mortality at 30 minutes was 11.8% and was significantly different than the control. Mortality exceeded 25% at 1 hour, as the value was calculated to be 68.5%, which was significantly different than the control.

**Conclusion:** Based upon a threshold of 25% to support a claim of starts killing, the data is adequate to support the following footnoted claim only on the dog product, 2596-RTI: "starts killing new fleas within 1 hour\*, \*48 hours after initial application."

#### **IV. ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:**

The proposed label efficacy claims are acceptable except for the comments and recommendations below:

A. For both products, killing claims against flea adults are only acceptable up to 30 days. Claims against breaking the flea life cycle or controlling flea eggs, and larvae up to 3 months are acceptable, but not adult control claims, or 3 month durations on the "general" flea claims as listed. This product is intended to be applied monthly, so the claim should not imply that this product will continue to kill re-infesting adult fleas after 30 days.

B. For the dog product only, 2596-RTI: The speed of kill claim for fleas must be revised as follows to include a footnoted claim: "starts killing new fleas within 1 hour\*, \*48 hours after initial application."

C. For the cat product, 2596-RTO, no speed of kill claims are supported.

D. For both products, remove claims stating that the product "prevents re-infestations/infestations in the home environment, premises etc." This claim implies that a pet applied product can control pests on premises, which is not supported. All variations of this claim pertaining to home premise infestations must be removed. Claims of killing flea eggs that may develop into adult fleas or preventing infestations by killing eggs on the animal are acceptable.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 417326; FILE SYMBOL No.: 2596-RTI; DECISION No.: 483630;  
PC Code(s): 129121, 129032, 105402; Action Code: R 315; FOOD Use: No

DATE: March 7, 2014

SUBJECT: Hartz Reference #143 (Dog product)

FROM: Akiva Abramovitch, Ph.D.  
Technical Review Branch / RD (7505P)

THROUGH: Shyam Mathur, Ph.D.  
Product Chemistry Team Leader  
Technical Review Branch / Registration Division (7505P)

TO: Carlyn Petrella / Richard Gebken, PM 10  
Insecticide Branch / Registration Division (7505P)

Company Name: The Hartz Mountain Corporation  
Formulation Type: Liquid Insecticide

## INTRODUCTION:

The applicant petitioned for a new non-food end use product registration. In support of the application, the applicant submitted product chemistry data corresponding to guideline 830 series, group A & group B. The product chemistry data for the proposed product have been submitted under MRID: 491157-01 through 03.

TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF dated March 11, 2014 (replaces the April 4, 2013 CSF).

## SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.80%), Methoprene (8.80%) and Pyriproxyfen (0.25%).
2. All of the source materials of the active ingredients are derived from registered sources.
3. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses.
4. Confidential Statement of Formula(s):

[X] Basic CSF Dated: March 11, 2014 (replaces the April 4, 2013 CSF).

DP BARCODE No.: 417326; FILE SYMBOL No.: 2596-RTI; DECISION No.: 483630;  
PC Code(s): 129121, 129032, 105402; Action Code: R 315; FOOD Use: No

5. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Flammable/Combustible

"Do not use or store near heat or open flame" correctly stated on the label.

Is the sub statement in compliance with PR Notice 97-6? ☒ Yes, if not, explain below:

- d. Label requires an additional Storage and Disposal statement: ☒ Yes ☐ No; if yes explain below:

Flammable/Combustible

"Do not use or store near heat or open flame" correctly stated on the label.

DP BARCODE No.: 417326; FILE SYMBOL No.: 2596-RTI; DECISION No.: 483630;  
 PC Code(s): 129121, 129032, 105402, Action Code: R 315; FOOD Use: No

# 6. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	491157-02
830.1600	Description of materials used to produce the product		X		A	491157-02
830.1650	Description of formulation process		X		A	491157-02
830.1670	Discussion on the formation of impurities		X		A	491157-02
830.1700	Preliminary analysis		X		A	491157-02
830.1750	Certified limits (158.350)	Standard certified limits	X		A	
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	491157-03

A = Acceptance, N = Not Acceptable, G = Data Gap,  
 W = Waiver Request, I = In Progress, NA = Not Applicable

DP BARCODE No.: 417326; FILE SYMBOL No.: 2596-RTI; DECISION No.: 483630;  
PC Code(s): 129121, 129032, 105402, Action Code: R 315; FOOD Use: No

7. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Light yellow liquid	A	491157-01
830.6315	Flammability	Flammable-Flash point 45C	A	491157-01
830.6316	Explodability	None- stable at normal and elevated temperatures	W	491157-01
830.7000	pH	7.3	A	e-mail attachment
830.7300	Density (units)	8.31 lb/gal at 25 C	A	491157-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,  
NA = Not applicable, I = In progress

**CONCLUSIONS:**

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. Basic CSF dated March 11, 2014 is acceptable.
2. The registrant must submit Storage Stability and Corrosion data to support the registration of this product.


## LABORATORY TEST REPORT

Person Requesting Work: L. Needham

Dept: CPD

Work Request Number: 14580

NBR: 4075/2

Work Done by: S. Hatzikyriakou 

Date: 3/10/14

### PH of Fipronil 3X Drops

<u>Sample</u>	<u>PH (at 25degC)</u>
Drops for Dogs 4074-23	7.3
Drops for Cats 4074-24	7.4

## **Abramovitch, Akiva**

---

**From:** SMcNear@hartz.com  
**Sent:** Monday, March 10, 2014 4:59 PM  
**To:** Abramovitch, Akiva  
**Cc:** DJones@hartz.com  
**Subject:** pH for Hartz Reference #143 and #144  
**Attachments:** PH in drops\_140310153056\_0001.pdf

Akiva,

As you have requested please find attached the pH results for the above listed products. My Manager of Regulatory Affairs, David Jones will send you the modified CSF tomorrow via email. Please let David know if you have additional questions or concerns.

Thank you for your assistance.

Best Regards,

Sean

Sean McNear  
Sr. Director Regulatory Affairs & Quality Assurance  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, New Jersey 07094  
TEL: 201-271-4800 x 7302  
FAX: 201-271-0357







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 10, 2014

NOTE TO RM 10 Carlyn Petrella

SUBJECT: Certification to Compliance with Child-Resistant Packaging Regulations EPA  
Registration Number: 2596-RTI DP 417505, Decision # 483630

Please note that EPA FILE NO: 2596-RTI (dog product) certification regarding child-resistant packaging (CRP) has been reviewed and is **acceptable** regarding compliance with the standards of 40 CFR 157.32. Acceptance of the CRP certification is based on the results for 0.5ml, 0.67ml, 1.34ml, 2.68, and 4.02ml sizes see MRID 48684601, 48684602, 48684603, 48684604, 48684605, and 48684606 in review by Breann Hanson March 29, 2012 [DP3999060, 399061, 399062, 399063; EPA Reg. No. 2596-RAG, 2596-RAU, 2596-RAL, and 2596-RAA]. The label dated January 23, 2014 on page 4 has the same directions for using the CRP as were used in Senior Adult Use Effectiveness (SAUE) testing per the Breann Hanson March 29, 2012 review as noted above.

Please place a copy of this note in the registration jacket for the above named product. Please advise the registrant that this **CRP certification is acceptable**. If you have any questions please contact me at (703)-308-7368.

A handwritten signature in cursive script that reads "Rosalind L. Gross".

Rosalind L. Gross



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

**CHILD RESISTANT PACKAGING CERTIFICATION STATEMENT**  
**Title 40 part 157 subpart B**

Registrant Name and Address:

The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

Products:

Hartz Reference # 143, EPA Reg. No. 2596- RTI

I certify that the packaging that will be used for the products listed above meet the standards of 40 CFR 157.32.

A handwritten signature in cursive script that reads "Sean McNear".

Sean McNear  
Sr. Director Regulatory Affairs  
& Quality Assurance

A handwritten date in cursive script that reads "April 29, 2013".

Date





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

February 24, 2014

**MEMORANDUM: REVISED DATA MATRIX FOR 2596-RTI**

Subject: Name of Pesticide Product: HARTZ® REFERENCE #143  
EPA Reg. No. /File Symbol: 2596-RTI  
DP Barcode: DP 417643  
Decision No.: 483630  
Action Code: R315  
PC Codes: 129121 (Fipronil: 9.8%)  
105402 (S-Methoprene: 8.8%)  
129032 (Pyriproxyfen: 0.25%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

*Byron T. Backus*  
*Feb-24-2014*  
*M. Hashmi*

To: Carlyn Petrella/Richard Gebken RM 10  
Insecticide Branch  
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORPORATION

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.80%
105401 (S)-Methoprene	8.80%
129032 Nylar	0.25%
<u>Other Ingredients:</u>	81.15%
TOTAL	100.00%

**ACTION REQUESTED:** The Risk Manager requests:

"Included please find: Updated Data Matrix..."

## BACKGROUND:

In response to the TRB review of December 11, 2013 the registrant has revised (date: January 23, 2014) the data matrix for 2596-RTI.

## COMMENTS AND RECOMMENDATIONS:

1. The registrant has cited MRID 44942005 to satisfy the dermal toxicity data requirement. In the review of December 11, 2013 it was stated that: *"MRID 44942005 is an acceptable dermal LD<sub>50</sub> study (with toxicity category IV results) that was used to support the registrations of 65331-4 and 65331-5. The registrant has the option of citing MRID 44942005 (which has been done in the application for 2596-RTO), citing another dermal LD<sub>50</sub> study conducted on a similar formulation, or conducting (and submitting) a dermal LD<sub>50</sub> study on 2596-RTI. If the dermal LD<sub>50</sub> study in MRID 44942005 is cited, 2596-RTI will be assigned to Toxicity Category IV for dermal toxicity."*
2. The registrant has cited MRID 45143901. In the review of December 11, 2013 it was stated that: *"In order to use the companion animal safety study in MRID 44942104 as supporting data, the registrant must also cite the additional material in MRID 45143901 which was used to upgrade the study in MRID 44942104 to acceptable."*
3. The registrant has cited MRID 42178309. In the review of December 11, 2013 it was stated that: *"The registrant should cite MRID 42178309 [Chapman, E. (1991) S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Lab Project Number: 91/0776. Unpublished study prepared by Life Science Research Ltd. 320 p.] in the data matrix under 870.7200 as none of their companion animal safety study citations addresses the subchronic (or chronic) toxicity of pyriproxyfen (nylar)."*
4. The data matrix dated January 23, 2014 adequately addresses all acute toxicity and companion animal safety study requirements for the registration of 2596-RTI.
5. There are no changes in the recommended precautionary and first aid labeling for 2596-RTI from that previously indicated in the TRB memorandum of December 11, 2013.



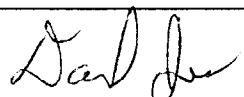
**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date January 23, 2014	EPA Reg. No./File Symbol 2596-RTI	Page 1 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094	Product Hartz Reference #143	

Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	43577715	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942105	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942106	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45612701	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620501	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620504	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620505	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620506	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866901	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866902	Merial	Pay	
Signature			Name and Title David Jones/Manager Regulatory Affairs	Date Jan. 23, 2014	



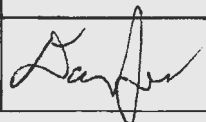
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**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date	January 23, 2014	EPA Reg. No./File Symbol	2596-RTI	Page 2 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #143		

Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	49115704	Hartz	Own	
830.1550	Product Identity and Composition	49115700	Hartz	Own	
830.1600	Description of Materials Used to Produce the Product	49115702	Hartz	Own	
830.1620	Description of the Production Process	49115702	Hartz	Own	
830.1650	Description of the Formulation Process	49115702	Hartz	Own	
830.1670	Discussion of Formation of Impurities	49115702	Hartz	Own	
830.1700	Viscosity	49115701	Hartz	Own	
830.1750	Certified Limits	49115702	Hartz	Own	
830.1800	Enforcement Analytical Method	49115703	Hartz	Own	
830.6302	Color	49115701	Hartz	Own	Self-certification
Signature			Name and Title David Jones/Manager Regulatory Affairs		Date Jan. 23, 2014





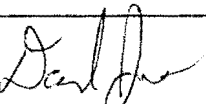
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**DATA MATRIX**

Date January 23, 2014	EPA Reg. No./File Symbol 2596-RTI	Page 3 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094	Product Hartz Reference #143	

Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical State	49115701	Hartz	Own	Self-certification
830.6304	Odor	49115701	Hartz	Own	Self-certification
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver	Hartz		
830.6315	Flammability	49115701	Hartz	Own	Self-certification
830.6316	Explodability	Waiver	Hartz		
830.6317	Storage Stability	To be submitted	Hartz		In progress
830.6319	Miscibility	49115702	Hartz	Own	
830.6320	Corrosion Characteristics	To be submitted	Hartz		In progress
830.6321	Dielectric Breakdown Voltage	Waiver	Hartz		
830.7000	pH	Waiver	Hartz		
Signature			Name and Title		Date
			David Jones/Manager Regulatory Affairs		Jan. 23, 2014



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**DATA MATRIX**

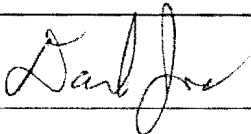
Date January 23, 2014

EPA Reg. No./File Symbol 2596-RTI

Page 4 of 5

Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr.,  
Secaucus, NJ 07094Product  
Hartz Reference #143

Ingredient Fipronil(S)-Methoprene/Pyriproxyfen

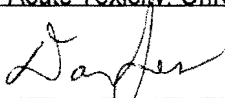
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	49115701	Hartz	Own	
870.1100	Acute Oral Toxicity	44942004	Merial	Pay	
870.1200	Acute Dermal Toxicity	44942005	Merial	Pay	
870.1300	Acute Inhalation Toxicity	Waiver requested	Waiver		
870.2400	Acute Eye Irritation	44942006	Merial	Pay	
870.2400	Acute Eye Irritation	48405805	Hartz	Own	
870.2500	Acute Dermal Irritation	44942007	Merial	Pay	
870.2600	Skin Sensitization	44942008	Merial	Pay	
870.7200	Companion Animal Safety	45143901	Merial	Pay	
870.7200	Companion Animal Safety	44942104	Merial	Pay	
Signature			Name and Title David Jones/Manager Regulatory Affairs	Date Jan. 23, 2014	190



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date January 23, 2014			EPA Reg. No./File Symbol 2596-RT1		Page 5 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #143		
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety	45612702	Merial	Pay	
870.7200	Companion Animal Safety	45620507	Merial	Pay	
870.7200	Companion Animal Safety	Waiver requested			
40 CFR 157 Subpart B	Child Resistant Package Testing	48684601	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684602	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684603	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684604	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684605	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684606	Hartz	Own	
870.4100	Acute Toxicity, Chronic toxicity	42178309	Sumitomo	FOR	
Signature			Name and Title David Jones/Manager Regulatory Affairs		Date Jan. 23, 2014

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1200 PENNSYLVANIA Ave., NW  
WASHINGTON, DC 20460-0001

CEPA Reg. No. 2596-RT1

REC'D FEB 0 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Thursday, January 16, 2014

**CERTIFIED MAIL: (Article Number 7008 3230 0000 9482 3753)**

**OPP Decision Number:** D-483630

Mr. David Jones  
Manager for Regulatory Affairs  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

**Subject:** Data Deficiency  
**EPA File Symbol:** 2596-RTI  
**Product Name:** Hartz Reference #143  
**Application Date:** September 23, 2013  
**EPA Receipt Date:** September 25, 2013

Dear Mr. Jones:

The application referred to above has been determined, pursuant to 40 CFR §152.105, not to be sufficiently complete to process. Therefore, your application is considered deficient. Citations for specific acceptable companion animal safety data, a CRP certification, and a revised data matrix, as specified in detail below, must be submitted to the Agency within 75 days of the date of this letter, before the processing of the application can be continued. **Upon receipt of the revised information, EPA will require a renegotiated PRIA due date that will allow the Agency sufficient time to complete the review process for this product.**

If, after 75 days, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion as noted below, the Agency will terminate any action on this application and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to this application must be submitted as a new application. The noted deficiencies for the referenced R310 new product; non-fast track application are as follows:

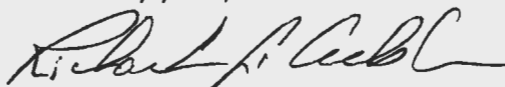
1. Specific companion animal safety data citations were not cited on the data matrix submitted along with this application. You must cite specific acceptable companion animal safety data by MRID along with a revised data matrix in order to support this application, or withdraw this application. Further review of this application cannot be made until the above deficiency has been resolved.
2. You must submit a CRP certification to support this application, or withdraw this application. Further review of this application cannot be made until the above deficiency has been resolved.
3. On the data matrix submitted with this application, you did not cite specific acceptable companion animal safety data that are needed to support this application. You must revise the data matrix by listing specific acceptable citations for companion animal safety data by MRID. Further review of this application cannot be made until the above deficiencies have been resolved.

**For reference purposes, the timeline for your re-submission is as follows:**

**Tuesday, April 1, 2013:** Revisions of all items identified in items #1 through #3 above must be provided to the Agency to further process this application. If you have not responded, or you subsequently failed to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn.

Please contact either Ms. Carlyn R. Petrella at 703-347-0439 or via e-mail at [Petrella.Carlyn@epa.gov](mailto:Petrella.Carlyn@epa.gov) or Mr. Richard J. Gebken at 703-305-6701 or via e-mail at [Gebken.Richard@epa.gov](mailto:Gebken.Richard@epa.gov) directly during the hours of 9:00 am to 5:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Richard J. Gebken", written in a cursive style.

Richard J. Gebken,  
Product Manager (10)  
Insecticide Branch,  
Registration Division (7504P)

002596-00RTI D483630



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

December 11, 2013

**SIMILARITY CLINIC MEMORANDUM**

Subject: Name of Pesticide Product: HARTZ<sup>®</sup> REFERENCE #143  
EPA Reg. No. /File Symbol: 2596-RTI  
DP Barcode: DP 416011  
Decision No.: 483630  
Submission #: 941688  
Action Code: R315  
PC Codes: 129121 (Fipronil: 9.80%)  
105401 (S-Methoprene: 8.80%)  
129032 (Pyriproxyfen: 0.25%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

*Byron T. Backus*  
*Dec -11- 2013*  
*JCR*

To: Richard Gebken RM 10  
Insecticide Branch  
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORPORATION

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.80%
105401 (S)-Methoprene	8.80%
129032 NyLar	0.25%
<u>Other Ingredients:</u>	<u>81.15%</u>
TOTAL	100.00%

**ACTION REQUESTED:** The Risk Manager requests:

"Similarity clinic..."



## BACKGROUND:

According to the Application for Registration (dated September 23, 2013): "PRIA Submission R315; New product registration application. Previously filed under File symbol 2596-RTL. MRIDs from data filed with that action cited herein." The registrant is not claiming similarity to an existing product. The registrant has included a data matrix (dated September 23, 2013) which cites the following MRIDs to satisfy the acute toxicity data requirements: 44942004 (acute oral LD<sub>50</sub>); 44942104 (acute dermal LD<sub>50</sub>); waiver requested (acute inhalation LC<sub>50</sub>); 44942006 and 48405805 (primary eye irritation); 44942007 (primary dermal irritation); and 44942008 (dermal sensitization). The cited companion animal safety studies (870.7200) are: 44942009, 44942104 [Note: 44942104 is also cited as a dermal LD<sub>50</sub> study in the data matrix], 45612702, 45620507, waiver requested, and 45612702 [this study is cited twice]. The proposed label has the signal word CAUTION and states that the product is to be used only on dogs and puppies 8 weeks or older. There are four weight categories: 5 to 22 lbs (0.67 mL/application); 23-44 lbs (1.34 mL/application); 45-88 lbs (2.68 mL/application); and 89-132 lbs (4.02 mL/application). In addition, there is a basic CSF dated 4/4/13.

## COMMENTS AND RECOMMENDATIONS:

1. According to OPPIN, 4 of the cited acute toxicity studies (MRIDs 44942004, 44942006, 44942007 and 44942008) were originally submitted to support 65331-4, one study (44942104) was submitted to support 65331-5, and one study (48405805) was originally submitted to support 2596-167, -168, and -169.
2. After comparing the CSFs of 65331-4 (and 65331-5) with the CSF (dated 10/28/2013) for 2596-RTI, TRB concludes that the acute toxicity (and companion animal safety) studies that were used to support the registrations of 65331-4 and/or 65331-5 will also support the registration of 2596-RTI. The presence of 0.25% pyriproxyfen [which has low toxicity to mammalian species] in 2596-RTI is not significant in terms of acute toxicity, so that studies conducted on the formulation(s) for 65331-4 and/or 65331-5 (which lack pyriproxyfen) can be used to define the acute toxicity of 2596-RTI. MRID 44942004 satisfies the acute oral LD<sub>50</sub> requirement (with assignment to toxicity category III); 44942006 [with the additional information in MRID 48405805, as noted below] satisfies the eye irritation study requirement (with assignment to toxicity category III); 44942007 satisfies the dermal irritation study requirement (toxicity category IV); and 44942008 satisfies the dermal sensitization study requirement (not a sensitizer).
3. The study in MRID 44942104 is a companion animal safety study [Nolan-Smith, S. (1999) Fipronil/(S)-Methoprene Topical Solution: Target Species Safety Study in the Dog: Interim Report: Lab Project Number: 1686/2: 1686/2-D1142: PR&D 0002101. Unpublished study prepared by Covance Laboratories Ltd. 266 p. {OPPTS 870.7200}], and cannot be used to satisfy the dermal LD<sub>50</sub> study data requirement. **MRID 44942005 is an acceptable dermal LD<sub>50</sub> study (with toxicity category IV results) that was used to support the registrations of 65331-4 and 65331-5. The registrant has the option of citing MRID 44942005 (which has**

*been done in the application for 2596-RTO), citing another dermal LD<sub>50</sub> study conducted on a similar formulation, or conducting (and submitting) a dermal LD<sub>50</sub> study on 2596-RTI. If the dermal LD<sub>50</sub> study in MRID 44942005 is cited, 2596-RTI will be assigned to Toxicity Category IV for dermal toxicity.*

4. The eye irritation study in MRID 48405805 was conducted on a formulation containing the following: Etofenprox – 55%; Piperonyl butoxide – 10%; MGK 264 – 1%; Methoprene – 2.3%; NyLar – 1%; other ingredients – 30.7%. *While this citation in itself does not satisfy the eye irritation study data requirement for the registration of 2596-RTI which has a label declaration of 9.8% fipronil, 8.8% methoprene and 0.25% pyriproxyfen, the registrant has stated in a cover letter dated September 23, 2013 that this study has been cited because it contains an inert which is also present in 2596-RTI. Based on the cited study in MRID 44942006, as well as the additional information in 48405805, 2596-RTI is assigned to Toxicity Category III for eye irritation.*
5. The study in MRID 44942009 [Clery, D. (1999) Fipronil/(S)-Methoprene/Topical/Solution/Target Species Safety Study in the Cat: Interim Final Report: Lab Project Number: GB011/99-001: PR&D 0023301. Unpublished study prepared by Biological Labs. Europe Ltd. 127 p. {OPPTS 870.7200}] was conducted on cats and cannot be used to support the use of 2596-RTI on dogs.
6. The study in MRID 44942104 [Nolan-Smith, S. (1999) Fipronil/(S)-Methoprene Topical Solution: Target Species Safety Study in the Dog: Interim Report: Lab Project Number: 1686/2: 1686/2-D1142: PR&D 0002101. Unpublished study prepared by Covance Laboratories Ltd. 266 p. {OPPTS 870.7200}] has been reviewed (TXR 5001488) with the following comments:

In a companion animal safety study (MRID 44942104) Frontline Plus [Active Ingredients: fipronil:10% w/v; (S)-methoprene:9% w/v] was topically applied (between the base of the skull and the shoulder blades) at dose levels of 0.133 mL/kg, 0.399 mL/kg, and 0.665 mL/kg, to groups of 6 male and 6 female beagle puppies (52-60 days old at initiation) on test Day 1 and again on test Day 29. Controls received no treatment.

No mortality was observed during the study period.

Overall, the observed clinical signs and changes in hematological and clinical chemistry parameters did not indicate significant treatment related adverse effects. The package labeling and application instructions indicate that the product is to be used on dogs or puppies 8 weeks or older and should not be used more frequently than once every 30 days. However, the package label does not specify the volume of product to be applied, and because the amounts applied in the study were indicated only as volume of product per kilogram body weight, it was not possible to verify that the amounts used in the study conformed to 1X, 3X and 5X of the amounts on the product label.

It is noted that doses are not stated on the proposed label. TRB concludes that the final dosages, as indicated on the label and as packaged in the applicator tubes, must be consistent with (no more than) the 1X application rate in this study (0.133 mL/kg).

It is also noted that this is an interim report, and there is insufficient information relating to the schedule of individual anthelmintic treatments (as well as the material administered), which should be provided in a final report (or as an amendment to this interim report). For these reasons, the study is currently classified as **Supplementary/Guideline** as a companion animal safety study (OPPTS 870.7200) in dogs (puppies).

Subsequently, additional information (MRID 45143901: Nolan-Smith, S. (1999) Fipronil/(S)-Methoprene Topical Solution: Target Species Safety Study in the Dog: Report Amendment: Amendment to Interim Report: Lab Project Number: 1686/2: 1686/2-D1142. Unpublished study prepared by Covance Labs., Ltd. 6 p. {OPPTS 870.7200}) was received and reviewed (TXR 5001489, memorandum dated July 11, 2000) with the following comment: "The classification of the Companion Animal Safety Study in MRID 44942104 is upgraded to acceptable."

***In order to use the companion animal safety study in MRID 44942104 as supporting data, the registrant must also cite the additional material in MRID 45143901 which was used to upgrade the study in MRID 44942104 to acceptable.***

7. The companion animal safety study in MRID 45612702 has been reviewed (TXR 5005723) with the following comments:

"In a companion animal safety study (MRID 456127-02), Frontline Plus (active ingredients: 10% w/v fipronil and 9% w/v {S}-methoprene) was topically applied (between the base of the skull and the shoulder blades at one or more spots) to eight week old dogs weighing less than 11 lbs at 1x, 3x and 5x the prepackaged use (0.67 mL/ puppy) dosage. Forty-eight beagle dogs (24/sex) were randomly allocated to one control and 3 treatment groups with 6 male and 6 female animals in each group. Controls received no treatment. The formulation was delivered from the marketed (0.67 mL) pipettes having 67 mg of fipronil and 60.3 mg of S-methoprene as 1x dosage. Puppies were exposed to the formulation only on Day 1, when they were at an average age of 57 (50 to 63) days and weighed 1.67 to 3.57 kg. .

"There were no deaths on the study, no local reaction on the application site and no treatment-related clinical signs in the measured parameters. There were no effects on rectal temperature, body weight, food and/or milk consumption, hematology or clinical chemistry.

"Gross necropsy and histopathology revealed no abnormalities, with possible exception of a few dermal effects at the treated sites (red area on the treated site in a few dogs which in one 3x male was 30 mm in diameter, and in another one 3x male was 10 mm in diameter, pages 84, 174, 176).

"A single topical application of fipronil (10% w/v) and (S)-methoprene (9% w/v) in a solution at 1x, 3x and 5 times the maximum recommended dose, when given to eight week old dogs (approx. 1.5-3.5 kg) showed no treatment related effects.

"This study (870-7200) is classified **Acceptable** in demonstrating a 5x margin of safety in dogs 8 weeks old or older and weighing less than 11 lbs." TRB has concluded that the minimum treatment weight can be based on the four lowest weight 5X male puppies and four lowest weight 5X female puppies. The mean weight of these eight puppies on Day 1 was 2.265 kg (or 4.99 lbs). This means that the minimum dog/puppy treatment weight is 5 lbs.

8. The companion animal safety study in MRID 45620507 [Godin, C.; Alva, R. (2000) ML-2,095,988 509T/Dog/Solution/Topical/Safety/Tolerance/Reproduction, Reactions: Final Report: Lab Project Number: PR&D 0020201: WEL 99885: PR&D 00202. Unpublished study prepared by White Eagle Toxicology Laboratory. 123 p.] was reviewed (TXR 5008387) with the following comments:

In a special (reproductive) companion animal safety study (MRID 45620507) ML-2,095,988 509T (a topical formulation containing 10% w/v fipronil and 9% w/v (S)-methoprene) was administered at 0X, 1X or 0.133 mL/kg (Group 2) and 3X or 0.399 mL/kg (Group 3) to groups of 12 adult female beagle dogs (bitches) prior to and during pregnancy, through parturition and to weaning of the puppies.

There was no indication of an adverse effect on any reproductive parameters (including gestation index, incidence of cesarean section, incidences of stillborn pups, incidences of pups dying between birth and weaning) or physiological parameters.

From information in the administrative materials for EPA Reg. No. 65331-3 (9.7% fipronil as sole active) and EPA Reg. No. 65331-5 (with the two actives fipronil at 9.8% and (S)-methoprene at 8.8%) the dosage rate for both products for dogs weighing 23-44 lbs (approx. 10-20 kg) is 1.34 mL/application so the label use application rate is approximately 0.067 - 0.134 mL/dog for dogs in this size range. In this study the 12 dogs in Group 2 (1X) had 0.133 mL/kg of the formulation applied directly to the skin at one spot between the base of the skull and the shoulder blades, while each of the 12 females in Group 3 (3X) received a total 0.399 mL/kg.

Although no dogs were dosed at 5X level, and no blood was taken for clinical chemistry and hematology measurements, the purpose of this study was to allow a label claim for use of at least two registered products (EPA Reg. Nos. 65331-3 and 65331-5) on breeding, pregnant and lactating bitches. TRB has previously reviewed a companion animal (dog) study for this formulation which included a 5X dosage group and measurements of clinical chemistry and hematology parameters

This study is classified as acceptable. The findings of this study are adequate to support the use of EPA Reg. Nos. 65331-3 and 65331-5 at the specified label use rates (varying

according to the weight of dog) at 28-day intervals on breeding, pregnant and lactating bitches. *This study citation would support the use of 2596-RTI on breeding, pregnant or lactating bitches; however it is noted that the proposed label (dated September 18, 2013) for 2596-RTI does not include these claims. The proposed label does include the FR Notice 96-6 (required in the absence of data indicating otherwise) specified pet product statement: "Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals."*

9. *The registrant should cite MRID 42178309 [Chapman, E. (1991) S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Lab Project Number: 91/0776. Unpublished study prepared by Life Science Research Ltd. 320 p.] in the data matrix under 870.7200 as none of their companion animal safety study citations addresses the subchronic (or chronic) toxicity of pyriproxyfen (nylar).*
10. We can accept a waiver request for the inhalation toxicity study requirement, with assignment of 2596-RTI to toxicity category IV by this exposure route.
11. If the registrant cites MRID 44942005 to satisfy the dermal toxicity data requirement, 2596-RTI would have the following acute toxicity profile:

Acute oral LD <sub>50</sub> (rat)	Toxicity category III	44942004 (cited)
Acute dermal LD <sub>50</sub> (rat)	(Toxicity category IV) <sup>a</sup>	(44942005) <sup>a</sup>
Acute inhalation LC <sub>50</sub>	Toxicity category IV	Waived
Primary eye irritation	Toxicity category III <sup>b</sup>	44942006 <sup>b</sup> , 48405805 <sup>b</sup> (cited)
Primary dermal irritation	Toxicity category IV	44942007 (cited)
Dermal sensitization	Not a sensitizer	44942008 (cited)

<sup>a</sup>Toxicity category IV if the registrant cites MRID 44942005 (as they did with 2596-RTO).

<sup>b</sup>Assigned to Toxicity category III on the basis of information in MRIDs 44942006 and 48405805.

12. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 2596-RTI, as obtained from the Label Review System:

**PRODUCT ID #:**           **002596-00178**

**PRODUCT NAME:**       **HARTZ® REFERENCE #143**

#### **PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:**   **CAUTION**

#### **Hazards to Humans and Domestic Animals:**

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

**First Aid:**

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**21-Day Screen Completed by**  
**Contractor**

**21-Day Expires on** 10-16-13

**Jacket #** 2596-RTI  
**MRID#** 492230

**Content Screen:** Recommend to Pass/Fail

**11-3 Review:** Pass/Fail/NA

**Overall Status:** Recommend to Pass/Fail

**Transfer This Jacket to:**

STEPHEN SCHAIBLE

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 9-25-13

Experts In-Processing Signature: B.B.

Date 9-27-13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>2596-RTI</u>		EPA Receipt Date: <u>9-25-13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with <u>PR Notice 86-5</u>			X		
8	Notice of Filing included with petitions					X



9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

- \* Deficiencies found in submitted studies: Confidentiality claim statement was not included in MRID 492230-01
- \* Inerts approved for non-food use
- \* corrections received 10/29
- \* submitted studies PASSED FRN 11-3 review
- \* Jacket PASSED

Mc

MRID: 492230

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

**Correa, Leah**

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**From:** DJones@hartz.com  
**Sent:** Tuesday, October 29, 2013 3:15 PM  
**To:** Correa, Leah  
**Cc:** Ashe, Anthony  
**Subject:** Re: Submission to EPA: Products Hartz Reference #143 and Hartz Reference #144 (EPA Reg# 2596-RTI and 2596-RTO)  
**Attachments:** No Data Conf Claims forms Hartz Ref 143 and 144 2013 Oct 29.pdf

Leah,

Per our discussion I have prepared a second page for each volume 2 submission listed below. I appreciate your taking the time to help me understand the requirement for waivers and options. Attached please find the scans of signed pages claiming no data confidentiality. They are scans of very similar forms with identical pagination and are intended one each for the volumes as the second page.

Thank you for your e-mail and taking the time to discuss the issues.

Sincerely,

David Jones  
Manager Regulatory Affairs  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094  
TEL: 201-271-4800 x 7414  
FAX: 201-271-0357

From: "Correa, Leah" <Correa.Leah@epa.gov>  
To: "djones@hartz.com" <djones@hartz.com>,  
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>  
Date: 10/28/2013 05:24 PM  
Subject: Submission to EPA: Products Hartz Reference #143 and Hartz Reference #144 (EPA Reg# 2596-RTI and 2596-RTO)

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Good Afternoon, Mr. Jones:

This e-mail is to address an issue found in the submitted studies associated with your applications for the registration of the products Hartz Reference #143 and Hartz Reference #144 (EPA Reg# 2596-RTI and 2596-RTO):

Hartz Reference # 143 (2596-RTI)

**MRID 492230-01: Volume 2 - Supplemental Information: Product: HARTZ Reference #143**

- You must include an acceptable statement of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study.

Hartz Reference # 144 (2596-RTO)

**MRID 492229-01: Volume 2 - Supplemental Information: Product: HARTZ Reference #144**

- You must include an acceptable statement of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study.

Please verify and send the corrections either by e-mail or through our secure fax line as soon as possible. If you have any questions, please do not hesitate to contact me.

Best Regards,

Leah

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**Leah M. Correa - EPA Contractor**

2777 S. Crystal Drive, S-4811, Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

September 27, 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-483630  
EPA File Symbol or Registration Number: 2596-RTI  
Product Name: HARTZ REFERENCE # 143  
EPA Receipt Date: 25-Sep-2013  
EPA Company Number: 2596  
Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES  
THE HARTZ MOUNTAIN CORPORATION  
400 PLAZA DRIVE  
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE  
TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR  
ONLY;;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST  
EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

No additional payment is due at this time. The Office of Pesticide Programs will make a determination on your discretionary refund request just prior to the time when a decision on this application is made.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

W  
{941688X~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies?      ☐ Fee Waiver?

☐ volpay    % Reduction: \_\_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.    10

Receipt No.

S-

941688

EPA File Symbol/Reg. No.

2596-RTI

Pin-Punch Date:

9/25/2013

☐ This item is NOT subject to FFS action.

**Action Code:**

Requested: R315

Granted: R315

Amount Due: \$ 8,000

**Parent/Child Decisions:**

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Steve Schauble

Date: 9/26/13

Remarks:

*submission of new product previously rejected under the  
tech screen deficiency screen*

*discretionary refund requested (Mick) similarity clinic*



United States

Environmental Protection Agency

Washington, DC 20460

X	Registration
	Amendment
	Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 2596-	2. EPA Product Manager Mr. Gebken	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) The Hartz Mountain Corp./ Hartz Reference #143	PM# 10	
5. Name and Address of Applicant (Include ZIP Code)  The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____  Product Name _____

## Section - II

<input type="checkbox"/>	Amendment - Explain below.	<input type="checkbox"/>	Final printed labels in response to Agency letter dated _____
<input type="checkbox"/>	Resubmission in response to Agency letter dated _____	<input type="checkbox"/>	"Me Too" Application.
<input type="checkbox"/>	Notification - Explain below.	<input checked="" type="checkbox"/>	Other - Explain below.

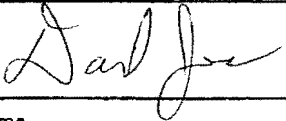
**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

PRIA Submission R315; New product registration application. Previously filed under File symbol 2596-RTL. MRIDs from data filed with that action cited herein.

### Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
* Certification must be submitted		If "Yes" Unit Packaging wgt. varies		No. per container see label	
		If "Yes" Package wgt		No. per container	
2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container see label		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product Printed		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other on doses _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Jones	Title Mgr Regulatory Affair	Telephone No. (Include Area Code) (201) 271-4800
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager Regulatory Affairs	
4. Typed Name David Jones	5. Date Sept. 23, 2013	



# Hartz

THE HARTZ MOUNTAIN CORPORATION  
400 PLAZA DRIVE  
SECAUCUS, NJ 07094

CORPORATION

No.

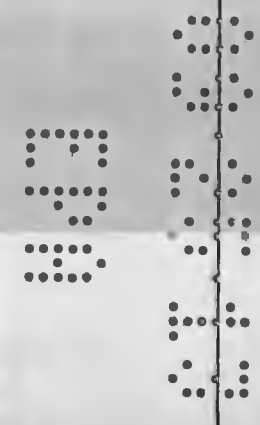
**323923**

DATE: 19-SEP-13

VENDOR NAME:

US ENVIRONMENTAL PROTECTION AGENCY

VENDOR NO: 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
2596-DOG	18-SEP-13	1000081505 P-	0.00	8,000.00
				

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT.

Thank You!

0.00

8,000.00

THIS CHECK IS PROTECTED BY A VOID PANTOGRAPH, MICROPRINT SIGNATURE LINE AND A HEAT SENSITIVE PADLOCK ICON. ADDITIONAL SECURITY FEATURES ARE LISTED ON BACK.

# Hartz

THE HARTZ MOUNTAIN CORPORATION  
400 PLAZA DRIVE  
SECAUCUS NJ, 07094

Bank of America

64-1278  
611 GA

No. **323923**

CHECK DATE  
19-SEP-13


CHECK NUMBER  
323923

CHECK AMOUNT  
\*\*\*\*\*8,000.00

PAY Eight Thousand Dollars And 00 Cents\*\*\*\*\*

TO  
THE  
ORDER  
OF

US ENVIRONMENTAL PROTECTION AGENCY  
PESTICIDE REGISTRATION SERVICE FEE  
PO BOX 979031  
ST LOUIS, MO 63197-9000





⑈ 3 2 3 9 2 3 ⑈ ⑆ [REDACTED] ⑆ [REDACTED] ⑈

# Receipt for Section 3

S: 341688

Product Type: ☒ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 2596 THE HARTZ MOUNTAIN CORPORATION

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 2596-RTI Product Name: HARTZ REFERENCE # 143

Me Too

Me Too

Section3:

Product Name:

Application Date: 23-Sep-2013

ip

OPP Rec'd Date: 25-Sep-2013

ip

Front End Date: 26-Sep-2013

ip

Risk Manager Send Date:

ip

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fas

New Ingredient:

Receipt Description:

New registraton application

Receipt Content

Study

ICSF

View/Edit

New Ingredient

New Ingredient

New Ingredient

New Ingredient

New Ingredient



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800  
REGULATORY AFFAIRS

September 23, 2013

FedEx Delivery

Document Processing Desk (Distribution Code-REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: New Pesticide Product Application, Hartz Reference #143

Dear Sir/Madam,

Enclosed please find a resubmission of a pesticide registration application package for Hartz Reference #143. This is an application previously submitted and rejected under EPA file symbol 2596-RTL. The label has been modified per direction from the agency. The Companion Animal Safety Study (CASS) citations have been expanded, an acute inhalation toxicity waiver request substantiation has been added, an acute eye toxicity study reference (Hartz's) and justification for a limited set of chemistry data waiver requests appended.

We have also included additional information on one inert that was discussed with EPA Staff on September 5, 2013. The cited data is submitted to support the use of the one inert as follows:

New formulas represented by 2596- RTA and RTL have been submitted to EPA for review. These formulas contain the inert ingredient [REDACTED]. Acute toxicity tests cited to support these formulas are based on formulas that do not contain this inert ingredient. To support the acceptable use of [REDACTED] in these formulas, a previously registered formula containing [REDACTED] at a significantly higher level (EPA Reg # 2596-169) was tested for acute eye irritation resulting in acceptable findings (Category III or higher). The MRID number for this study is 48405805.

Considering the amount of [REDACTED] in this formula, the following comparison of formula content is presented:

Given the significantly lower concentration of [REDACTED] for 2596-RTA and 2596-RTL vs 2596-169, no increase in toxic response from [REDACTED] is anticipated vs results for EPA Reg # 2596-169.

\*Inert ingredient information may be entitled to confidential treatment\*

Hartz Reference #143

September 23, 2013

Page 2

Enclosed is check no. 323923 payable to the US Environmental Protection Agency in the amount of \$8000. This is to cover the PRIA Code R315. Per instruction from Marty Monell, we respectfully request a partial refund of the fee previously paid for the initial filing (see meeting notes in Volume 2). Discussed in the same meeting evidenced in the attached summary we request an accelerated processing of this application. Consideration of this question is appreciated.

Direct contact by phone or e-mail is welcomed if I can assist in the processing of information presented in this package.

Sincerely,



David Jones  
Manager Regulatory Affairs  
The Hartz Mountain Corporation  
(201) 271-4800, ext. 7414  
[djones@hartz.com](mailto:djones@hartz.com)

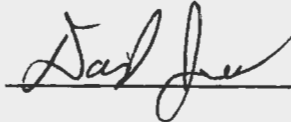
Encl.

# TRANSMITTAL DOCUMENT

**Submitter:**

The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

Company Contact:



Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: [djones@hartz.com](mailto:djones@hartz.com)

**Regulatory Action in Support of Which This Package is Submitted:**

EPA Reg. No. 2596-XXX; HARTZ Reference #143; PRIA Code R315

Filing for new end-use non-food animal product with data waiver requests.

**Submission Date:**

09/23/2013

**List of Submitted Documents:**

<b>Volume 1</b>	<b>Administrative Materials</b>	<b>(3 copies)</b>
	Application Form	
	Confidential Statement of Formula	
	Formulator's Exemption Statement	
	Data Matrix	
	Data Matrix, confidential public copy	
	Certification with Respect to Data	
	List of Data Submitters Sent Offer to Pay Letters	
	Proposed Label Text (Five copies)	
	Child Resistant Packaging Certification Statement	

**Volume 2**

**Supplemental Information**

**(3 copies)**

**Summary of Meeting with EPA Sept. 5, 2013**

**Waiver Request, Scheuplein**

**Waiver Request, Hauswirth**

**Acute Inhalation Toxicity Waiver Request**

**Chemistry Data Waiver Requests**



United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address  The Hartz Mountain Coporation 400 Plaza Drive Secaucus, NJ 07094	EPA File Symbol/Registration Number 2596-RTL
	Product Name Hartz Reference # 143
	Date of Confidential Statement of Formula (EPA Form 8570-4) 04/04/2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

**Fipronil, (S)-methoprene, Pyriproxfen**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

**Source**

Active Ingredient	Product Name	Registration Number
Fipronil; CAS #122068-37-3		
(S)-Methoprene; CAS # 65733-16-6		
Pyriproxifen; CAS # 095737-68-1		
Signature 	Name and Title Sean McNear, Sr. Dir. Reg Affairs	Date 05/13/2013

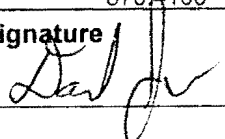
EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy

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**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date Sept. 23, 2013			EPA Reg. No./File Symbol 2596-		Page 5 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #143		
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety	45612702	Merial	Pay	
870.7200	Companion Animal Safety	45620507	Merial	Pay	
870.7200	Companion Animal Safety	Waiver requested			
870.7200	Companion Animal Safety	45612702	Merial	Pay	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684601	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684602	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684603	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684604	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684605	Hartz	Own	
40 CFR 157 Subpart B	Child Resistant Package Testing	48684606	Hartz	Own	
870.4100	Acute Toxicity, Chronic toxicity	42178309	Sumitomo	FOR	
Signature 		Name and Title David Jones/Manager Regulatory Affairs		Date Sept. 23, 2013	

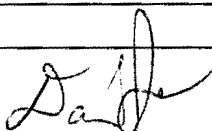




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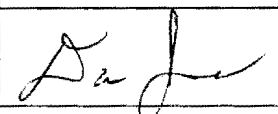
Date Sept. 23, 2013		EPA Reg. No./File Symbol 2596-		Page 1 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #143			
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	43577715	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942105	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	44942106	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45612701	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620501	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620504	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620505	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45620506	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866901	Merial	Pay	
810.3300	Treatments to Control Pests of Humans and Pets	45866902	Merial	Pay	
Signature			Name and Title David Jones/Manager Regulatory Affairs		Date Sept. 23, 2013



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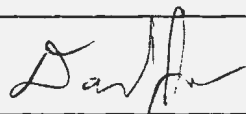
Date Sept. 23, 2013			EPA Reg. No./File Symbol 2596-	Page 2 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #143		
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Treatments to Control Pests of Humans and Pets	49115704	Hartz	Own	
830.1550	Product Identity and Composition	49115700	Hartz	Own	
830.1600	Description of Materials Used to Produce the Product	49115702	Hartz	Own	
830.1620	Description of the Production Process	49115702	Hartz	Own	
830.1650	Description of the Formulation Process	49115702	Hartz	Own	
830.1670	Discussion of Formation of Impurities	49115702	Hartz	Own	
830.1700	Viscosity	49115701	Hartz	Own	
830.1750	Certified Limits	49115702	Hartz	Own	
830.1800	Enforcement Analytical Method	49115703	Hartz	Own	
830.6302	Color	49115701	Hartz	Own	Self-certification
Signature			Name and Title		Date
			David Jones/Manager Regulatory Affairs		Sept. 23, 2013



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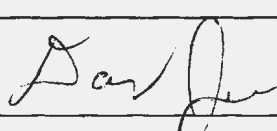
Date Sept. 23, 2013			EPA Reg. No./File Symbol 2596-		Page 3 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #143		
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303	Physical State	49115701	Hartz	Own	Self-certification
830.6304	Odor	49115701	Hartz	Own	Self-certification
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver	Hartz		
830.6315	Flammability	49115701	Hartz	Own	Self-certification
830.6316	Explosibility	Waiver	Hartz		
830.6317	Storage Stability	To be submitted	Hartz		In progress
830.6319	Miscibility	49115702	Hartz	Own	
830.6320	Corrosion Characteristics	To be submitted	Hartz		In progress
830.6321	Dielectric Breakdown Voltage	Waiver	Hartz		
830.7000	pH	Waiver	Hartz		
Signature			Name and Title David Jones/Manager Regulatory Affairs		Date Sept. 23, 2013



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Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	49115701	Hartz	Own	
870.1100	Acute Oral Toxicity	44942004	Merial	Pay	
870.1200	Acute Dermal Toxicity	Should be 44942005? 44942104	Merial	Pay	
870.1300	Acute Inhalation Toxicity	Waiver requested	Waiver		
870.2400	Acute Eye Irritation	44942006	Merial	Pay	
870.2400	Acute Eye Irritation	48405805	Hartz	Own	
870.2500	Acute Dermal Irritation	44942007	Merial	Pay	
870.2600	Skin Sensitization	44942008	Merial	Pay	
870.7200	Companion Animal Safety	44942009	Merial	Pay	
870.7200	Companion Animal Safety	44942104 ?	Merial	Pay	
Signature			Name and Title		Date
			David Jones/Manager Regulatory Affairs		Sept. 23, 2013



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The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Hartz Reference #143		

Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
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			Merial	Pay	
			Merial	Pay	

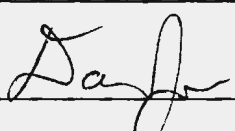
Signature		Name and Title	Date
		David Jones/Manager Regulatory Affairs	Sept. 23, 2013



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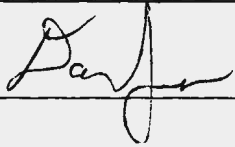
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Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	Self-certification
Signature			Name and Title		Date
			David Jones/Manager Regulatory Affairs		Sept. 23, 2013



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Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status Note
			Hartz	Own Self-certification
			Hartz	Own Self-certification
			Hartz	
			Hartz	Own Self-certification
			Hartz	
			Hartz	
			Hartz	Own In progress
			Hartz	Own
			Hartz	
			Hartz	In progress
			Hartz	
			Hartz	
Signature			Name and Title David Jones/Manager Regulatory Affairs	Date Sept. 23, 2013



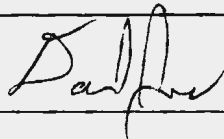
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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**DATA MATRIX**

Date Sept. 23, 2013	EPA Reg. No./File Symbol 2596-	Page 4 of 5
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #143

Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	
			Merial	Pay	
			Merial	Pay	
			Waiver		
			Merial	Pay	
			Hartz	Own	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
			Merial	Pay	
Signature			Name and Title		Date
			David Jones/Manager Regulatory Affairs		Sept. 23, 2013





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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**DATA MATRIX**

Date Sept. 23, 2013		EPA Reg. No./File Symbol 2596-		Page 5 of 5	
Applicant's/Registrant's Name & Address: The Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #143			
Ingredient Fipronil/(S)-Methoprene/Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Merial	Pay	
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			Merial	Pay	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Sumitomo	FOR	
Signature <i>David Jones</i>			Name and Title David Jones/Manager Regulatory Affairs		Date Sept. 23, 2013



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

**LIST OF DATA SUBMITTERS SENT OFFER-TO-PAY LETTERS**

(Below information comes from <http://www.epa.gov/opppmsd1/DataSubmittersList/>)

Fipronil (CAS 120068-37-3)  
S-Methoprene (CAS 65733-16-6)

Merial Limited

3239 Satellite Blvd.  
Bldg. 500  
Duluth, GA 30096

**Hartz® Reference # 143**Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)  
 Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)  
 First Defense Pro™ for Dogs (&) (and Puppies)  
 FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)  
 First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

**FRONT PANEL**

*[Each of the above brands will be packaged in the weight classes designated below:]*

Weighing 5 to 22 lbs.  
 Weighing 23 to 44 lbs.  
 Weighing 45 to 88 lbs.  
 Weighing 89 - 132 lbs.

**ACTIVE INGREDIENTS:**

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
<b>OTHER INGREDIENTS .....</b>	<b>81.15%</b>
<b>TOTAL .....</b>	<b>100.00%</b>

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See back panel for additional precautionary statements.

**NET CONTENTS:**

<b>For use ONLY on Dogs and Puppies 8 weeks and older Weighing:</b>	<b>Net Contents (Each tube)</b>
5 to 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



*[Cat Warning: A cat prohibition icon will appear on the front panel and back panel.]*

**DO NOT USE ON CATS**

**BACK PANEL**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

**PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

**FIRST AID**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and

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veterinary health concerns, emergency medical treatment information or pesticide incidents.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

#### **READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER**

**DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS**

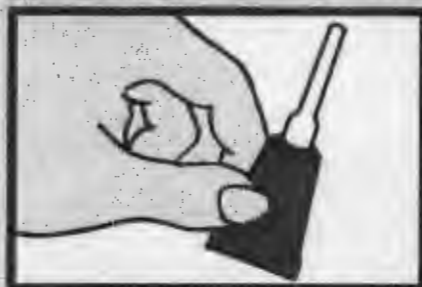
**DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT**

**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS**

**THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER**



**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



**1** Remove one applicator tube from the package and hold in an upright position pointed away from your face.



**2** Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



**3** Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

**4** Repeat every month.

**SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.

**PESTICIDE STORAGE:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

**INDIVIDUAL TUBE TEXT**

*[Product name]*

Only for use on DOGS AND PUPPIES 8 WEEKS OR OLDER

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.70%), (S)-Methoprene (8.8%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

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**OPTIONAL/ALTERNATE LABEL TEXT**

---

[Adult Fleas]

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations after application

Prevents establishment of new infestations after application in the home environment

Prevents establishment of new infestations after application on premises

Prevents establishment of new infestations in the home environment

Prevents establishment of new infestations on premises

Starts killing fleas within 30 minutes (mins) (and lasts for 30 days) (1 month) (4 weeks)

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)



Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)  
Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a-month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home environment (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults on premises (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) technology prevents re-infestation

Dual insect growth regulator (IGR) technology prevents re-infestation in the home environment

Dual insect growth regulator (IGR) technology prevents re-infestation on premises

Contains two unique ingredients to prevent flea infestations

Contains two unique ingredients to prevent flea infestations in the home environment

Contains two unique ingredients to prevent flea infestations on premises

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

Waterproof

Effective after bathing

---

Effective after exposure to water

Easy spot on topical applicator

Patents Pending

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen)

(Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

New (Formula) *(claim to be removed after 6 months)*

Only for dogs and puppies 8 weeks of age or older

Specially formulated for dogs and puppies 8 weeks of age or older

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

(Pro-cision Flo® Applicator)

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose \_\_\_\_\_

Hartz® Reference #143  
EPA Reg. No.: 2596-  
MASTER LABEL- -

September 18, 2013

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Second Dose \_\_\_\_\_  
Third Dose \_\_\_\_\_

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar® - Registered Trademark of McGlaughlin Gormley King Company)

EPA Reg. No. 2596-  
EPA Est. No. 2596-OH-1



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

**CHILD RESISTANT PACKAGING CERTIFICATION STATEMENT**  
**Title 40 part 157 subpart B**

Registrant Name and Address:

The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

Products:

Hartz Reference # 143, EPA Reg. No. 2596-

I certify that the packaging that will be used for the products listed above meet the standards of 40 CFR 157.32.

Sean McNear  
Sr. Director Regulatory Affairs  
& Quality Assurance

Date

# Volume 1 – Administrative Materials

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**Product:** HARTZ Reference #143

**Submitter:**

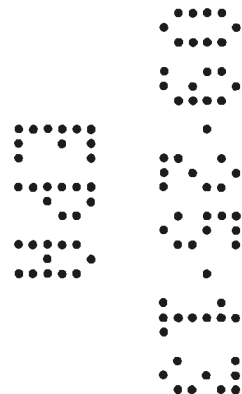
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

**Submission Date:**

09/23/2013

**List of Submitted Documents:**

<b>Volume 1</b>	<b>Administrative Materials</b>
	Application Form
	Confidential Statement of Formula
	Formulator's Exemption Statement
	Data Matrix
	Data Matrix, confidential public copy
	Certification with Respect to Data
	List of Data Submitters Sent Offer to Pay Letters
	Proposed Label Text (Five copies)
	Child Resistant Packaging Certification Statement





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094, 201-271-4800	EPA Registration Number/File Symbol 2596-
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-Methoprene and Pyriproxyfen	Date April 30, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Residential	Product Name Hartz Reference #143

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date April 30, 2013	Typed or Printed Name and Title Sean McNear, Sr. Director Regulatory Affairs
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